



# Silom Community Clinic CRS Update for MTN-017

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# Presentation Outline

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



# Study Progress: Milestones

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- Date of First and Last Screening
  - First: 28 June 2014
  - Last: 30 Sep 2014 (1 Oct 2014 was not enrolled due to accrual target had already been met)
- Date of First and Last Enrollment
  - First: 9 July 2014
  - Last: 22 Oct 2014
- Date of Last Follow Up Visit (Projected)
  - 22 April 2015 (last call-in on 29 April 2015)

# Study Progress: Accrual

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- Number of Participants Screened
  - 223 approached -> 52 discussed -> 32 screened
- Number of Participants Enrolled
  - 24 with no replacement
- Overall Screening to Enrollment Ratio
  - 32:24 (1.3:1)
- Duration of Accrual (months)
  - 4 months (15 weeks)
- Number of ineligibility
  - 8 [rectal GC/CT infection (2), use of study-prohibited medicine (2), high creatinine clearance (1), other rectal infections (2), met accrual target (1)]



# Study Progress: Retention

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- Missed Visits to date (#) – None
- Loss-to-Follow Up to date (#) – None



# Best Practices

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- Careful selection of participants via phone call (told existing clients of this new study and asked them to come in for more discussion; usually took 2 calls)
- Face-to-face discussions (usually 2 times per person)
- Triple mode of communication for study adherence (SMS, phone call, and LINE chat)

We will continue to use the above practices in the future in addition to Facebook messenger and LINE stickers



# Retention Challenges

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- Challenge #1: Urgent work assignment at the time of scheduled visit
- Challenge #2: Study visit schedule is too strict, especially for rectal biopsy
- Challenge #3: Rectal biopsy visit at BIDI is during usual office hour, requiring taking leave/medical certificate
- Challenge #4: Time taken in each study visit is too long
- Challenge #5: Long national holidays impede complying with strict study visit schedule (manageable)

# Retention Strategies

## □ Strategy #1: Participant booklet with Study Visit Time Table



MTN-017 Visit Time Table

Pre-ENR	Period 1				Period 2			Period 3			END
	Week -1	Week 0	Week 4	Week 8	Week 9	Week 13	Week 17	Week 18	Week 22	Week 26	
Screening Visit 1 30	Enrollment Initial Visit 1 0	Mid Period 1 Visit 2 30 (26-30)	Mid Period 1 Visit 3 30 (26-30)	Mid Period 1 Visit 4 30 (26-30)	Initial Period 2 Visit 5 60 (54-60)	Mid Period 2 Visit 6 60 (54-60)	Mid Period 2 Visit 7 60 (54-60)	Initial Period 3 Visit 8 120 (114-120)	Mid Period 3 Visit 9 120 (114-120)	Mid Period 3 Visit 10 120 (114-120)	Termination No Visit
Main study (1 hour) - Consent - Demograph - Counseling - Physical - Blood - Rectal - Urine - \$ 800	Main study (1 hour) - CASI - Counseling - Physical - Blood - Rectal - Randomize - Products - \$ 800	Main study (1 hour) - Counselint - Physical - Blood - Rectal - Products - \$ 800	Main study (1 hour) - CASI - Counseling - Physical <sup>a</sup> - Blood - Rectal - Products - \$ 800	Main study (1 hour) - CASI - Counseling - Physical <sup>a</sup> - Blood - Rectal - Products - \$ 800	Main study (1 hour) - Counseling - Physical <sup>a</sup> - Blood <sup>a</sup> - Rectal - Products - \$ 800	Main study (1 hour) - Counselint - Physical <sup>a</sup> - Blood - Rectal - Products - \$ 800	Main study (1 hour) - CASI - Counseling - Physical <sup>a</sup> - Blood - Rectal - Products - \$ 800	Main study (1 hour) - Counseling - Physical <sup>a</sup> - Blood <sup>a</sup> - Rectal - Products - \$ 800	Main study (1 hour) - Counselint - Physical <sup>a</sup> - Blood - Rectal - Products - \$ 800	Main study (1 hour) - CASI - Counseling - Physical - Blood - Rectal - Urine - Products - \$ 800	Main study (0 hour)
	SMS (W0-3) (2 minutes) - Daily SMS - \$ 30/SMS <sup>a</sup> - \$ 30 bonus <sup>a</sup>	SMS (W4-7) (2 minutes) - Daily SMS - \$ 30/SMS <sup>a</sup> - \$ 30 bonus <sup>a</sup>			SMS (W9-12) (2 minutes) - Daily SMS - \$ 30/SMS <sup>a</sup> - \$ 30 bonus <sup>a</sup>	SMS (W13-16) (2 minutes) - Daily SMS - \$ 30/SMS <sup>a</sup> - \$ 30 bonus <sup>a</sup>		SMS (W18-21) (2 minutes) - Daily SMS - \$ 30/SMS <sup>a</sup> - \$ 30 bonus <sup>a</sup>	SMS (W22-25) (2 minutes) - Daily SMS - \$ 30/SMS <sup>a</sup> - \$ 30 bonus <sup>a</sup>		
	FU Phone Call (1-5 minutes) - @week 2				FU Phone Call (1-5 minutes) - @week 10			FU Phone Call (1-5 minutes) - @week 20			FU Phone Call (Call in) - @week 27
Interview <sup>b</sup> (15 minutes) - Consent		Interview <sup>b</sup> (30 minutes) - Phone call - \$ 500									
Special study <sup>c</sup> (45 minutes) - Consent	Special study <sup>c</sup> (2 hours) - Rectal fluid - Rectal Enema - Rectal biopsy - \$ 2,000		Special study <sup>c</sup> (2 hours) - Blood PK - Rectal fluid - Rectal Enema - Rectal biopsy - \$ 2,000				Special study <sup>c</sup> (2 hours) - Blood PK - Rectal fluid - Rectal Enema - Rectal biopsy - \$ 2,000			Special study <sup>c</sup> (2 hours) - Blood PK - Rectal fluid - Rectal Enema - Rectal biopsy - \$ 2,000	
			FU Phone Call <sup>d</sup> (1-5 minutes) - @72 hours				FU Phone Call <sup>d</sup> (1-5 minutes) - @72 hours				
Max x 800 (2 hours)	Max x 2,860 (2 hours)	Max x 2,260 (1.5 hours)	Max x 3,790 (3 hours)		Max x 960 (1 hour)	Max x 1,760 (1.5 hours)	Max x 3,790 (3 hours)	Max x 960 (1 hour)	Max x 2,760 (1.5 hours)	Max x 3,760 (3 hours)	x 0 (0 hour)





# Retention Strategies

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- Strategy #2: Give participants calculated visit schedule
- Strategy #3: Reminder SMS one week prior to the visit
- Strategy #4: Reminder phone call one day prior to the visit
- Strategy #5: Computerized system tracking the reminder activities and scheduled visits
- Strategy #6: Alternative assigned phone number and Line chat for visit inquiries
- Strategy #7: Weekly to almost daily communications to confirm the visits



# Adherence Challenges

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- Challenge #1: Travelling outside of the mobile service area impeded the ability to consult instantly and to be reminded via FrontlineSMS
- Challenge #2: Improper functioning of FrontlineSMS impeded the ability to be reminded
- Challenge #3: RAI regimen had no reminder mechanism
- Challenge #4: Applicator design/quality impeded the use
- Challenge #5: One case misunderstood the wash-out period for product-use period (too many periods)



# Adherence Strategies

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- Strategy #1: Thorough adherence counselling
- Strategy #2: FU phone call 2-3 days after Period Initiation Visit helped remind the regimen



# Going Forward

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- How will high data quality be maintained?
  - Thorough and meticulous QC system and timely consultation within site and with PSRT/MTN CORE
  - Raise staff moral to keep-up the good work (compliment, praise, award)
  
- How will high participant retention continue?
  - Thorough and meticulous reminder system
  - Continuous study adherence counselling



# Going Forward

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- How will high visit and product use adherence be sustained?
  - Thorough and meticulous reminder system
  - Continuous study adherence counselling
  - Continuous product use adherence counselling
  - Open line of communication between assigned study staff (Site Coordinator) and participants (phone call and LINE chat)
  - Continue fixing FrontlineSMS to be used as reminder

# Lessons Learned

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- Rectal biopsy collection was well-accepted
- Rectal biopsy scars take several months to heal (need to tell this to participants from the beginning)
- Multiple methods of reminder/report are needed due to
  - Forgetfulness to refill the pre-paid phone credit impeded the ability to report correctly/in a timely manner
- Thorough and repeated adherence counselling is needed due to
  - Confusion of study periods and regimens

# Others

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- ❑ Defected gel applicators (unexpected incident caused unplanned solution)



# Others

- The tip of the applicator is quite sharp, sometimes hurting the participants
- One-month supply of the gel applicators plus condoms and lubricants required a large bag





# Others

- Inability to self-identify study-prohibited medications due to variety of generic tablet appearance
  - Strategy #1: LINE chat to consult about study-prohibited medications
  - Strategy #2: Advise to hold off any uncertain medication if not urgent





Any Questions?

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