GeneXpert Study Data Collection

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MTN Virology Core

Regional Meeting Lab Breakout

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Background

- MTN has switched HIV confirmatory testing from the Western Blot to the Geenius
- This will greatly decrease time from positive rapid to confirmation test
- When the Geenius is negative or indeterminate, participants will still need to wait for an RNA result

Background

- Cepheid has introduced a RNA test for the GeneXpert. It is currently CE marked with plans for FDA approval in 2017
- MTN would like evaluate if same-day HIV RNA testing at sites where there is a GeneXpert available at the clinic reduces time to final HIV status determination for participants who may be acutely infected with HIV

Study Questions

- Can site visit flow/laboratory capacity accommodate simultaneously performing a STAT HIV confirmatory test (Geenius) and viral load (GeneXpert)?

- Are participants willing to wait in the clinic for a same day RNA result?

Study Design

- Gene Xpert sites
  - WRHI
  - CAPRISA
  - Lilongwe
- Control sites
  - Verulam
  - Capetown
  - Blantyre

How Will We Collect the Data?

- Data reported on CRFs can be collected from SCHARP
- Specific data (like the time that tests were performed) will need to be collected directly from sites

Study Design

- When enrolled participants have a positive rapid, GeneXpert sites will proceed directly to GeneXpert RNA and Geenius
  - If the Geenius result is negative or indeterminate, the RNA will be used for the algorithm
  - If the Geenius result is positive, it will be used for participant treatment

SCHARP Data

- SCHARP will send LC an alert any time an enrolled participant has a positive HIV rapid.
- Alert will include PTID, Visit number, Date of rapid result, and rapid results.
- This will help us follow-up any participants with potential GeneXpert results

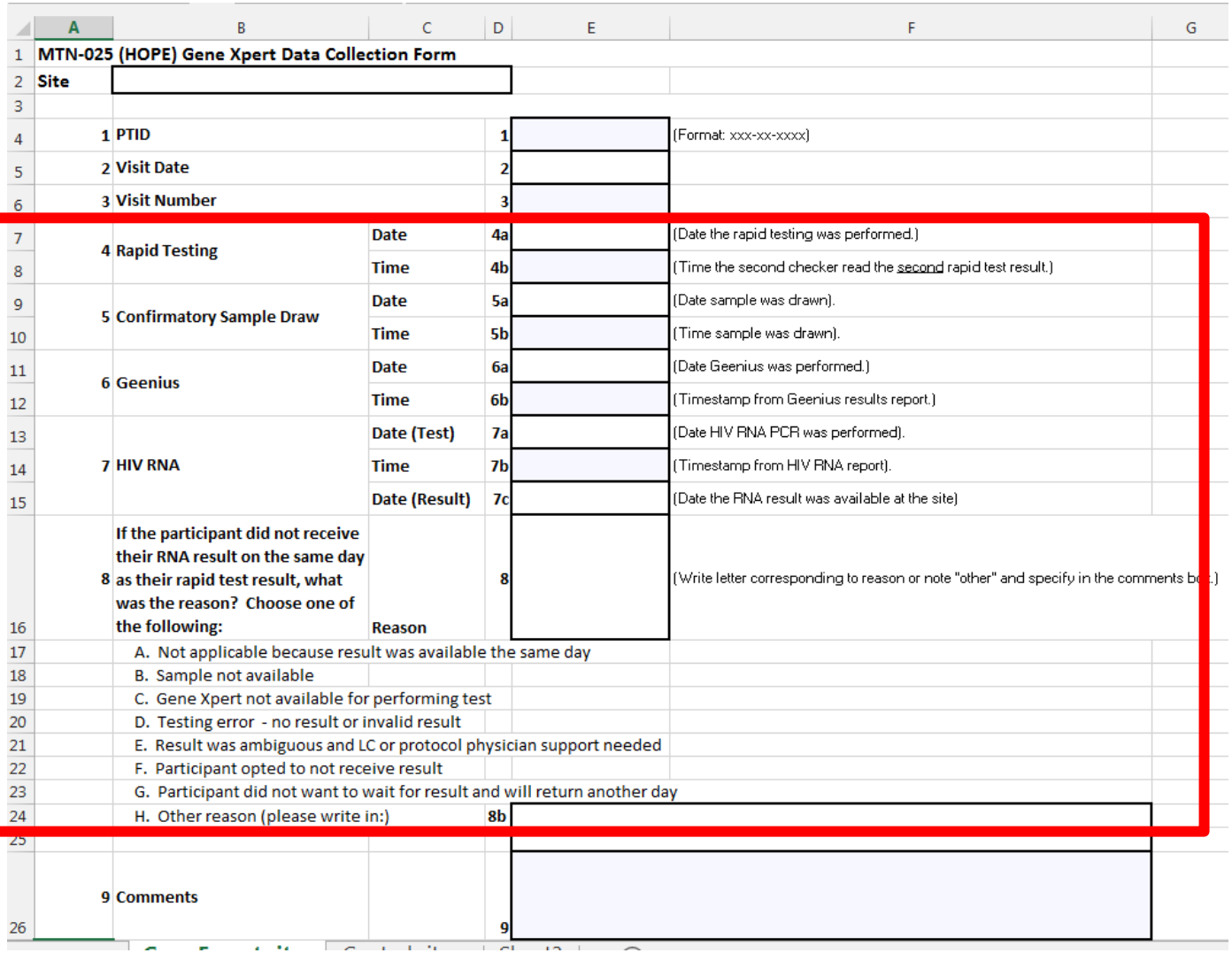
SCHARP Data

- SCHARP can also provide:
  - Date of positive rapid test
  - Date of Geenius run
  - # Days between first positive rapid and HIV RNA
  - Number of interim visits after first positive rapid
  - Days of product hold before resuming product (for participants confirmed as HIV negative)

Site Data

- SCHARP will not have exact times tests were conducted or results were obtained
- This will be important for calculating efficiency for use of GeneXpert
- Sites will have an Excel form to fill out and send directly to LC

Excel Form



	A	B	C	D	E	F	G
1	**MTN-025 (HOPE) Gene Xpert Data Collection Form**						
2	**Site**						
3							
4	**1**	**PTID**		**1**		(Format: xxx-xx-xxxx)	
5	**2**	**Visit Date**		**2**			
6	**3**	**Visit Number**		**3**			
7	**4**	**Rapid Testing**	**Date**	**4a**		(Date the rapid testing was performed.)	
8			**Time**	**4b**		(Time the second checker read the second rapid test result.)	
9	**5**	**Confirmatory Sample Draw**	**Date**	**5a**		(Date sample was drawn).	
10			**Time**	**5b**		(Time sample was drawn).	
11	**6**	**Geenius**	**Date**	**6a**		(Date Geenius was performed.)	
12			**Time**	**6b**		(Timestamp from Geenius results report.)	
13	**7**	**HIV RNA**	**Date (Test)**	**7a**		(Date HIV RNA PCR was performed).	
14			**Time**	**7b**		(Timestamp from HIV RNA report).	
15			**Date (Result)**	**7c**		(Date the RNA result was available at the site)	
16	**8**	**If the participant did not receive their RNA result on the same day as their rapid test result, what was the reason? Choose one of the following:**	**Reason**	**8**		(Write letter corresponding to reason or note "other" and specify in the comments be...)	
17		A. Not applicable because result was available the same day					
18		B. Sample not available					
19		C. Gene Xpert not available for performing test					
20		D. Testing error - no result or invalid result					
21		E. Result was ambiguous and LC or protocol physician support needed					
22		F. Participant opted to not receive result					
23		G. Participant did not want to wait for result and will return another day					
24		H. Other reason (please write in:)		**8b**			
25							
26	**9**	**Comments**		**9**			

Item 4: Rapid Testing

- **Date** the rapid test was performed
- **Time** the second checker read the second rapid test

Item 5: Confirmatory Sample Drawn

- **Date** the blood sample for confirmatory testing was drawn
- **Time** the blood sample for confirmatory testing was drawn

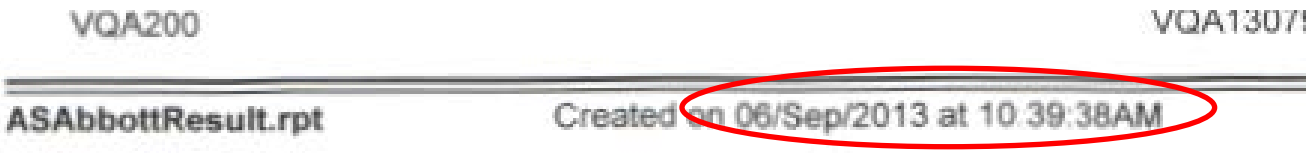
***Not the sample for rapid**

Item 6: Geenius

- **Date** Geenius was performed
- **Time** from Geenius results report timestamp

Item 7: HIV RNA

- **Test Date** HIV RNA PCR was performed
- **Time** from HIV RNA report timestamp
- **Results Date** that the RNA result was available at the site



Item 8: If the participant did not receive their RNA result on the same day as their rapid test result, what was the reason?

A. Not applicable because result was available the same day
B. Sample not available
C. GeneXpert not available for performing test
D. Testing error - no result or invalid result
E. Result was ambiguous and LC or protocol physician support needed
F. Participant opted to not receive result
G. Participant did not want to wait for result and will return another day
H. Other reason (please write in:)

Form Submission

- Email completed form to MTN LC within 2 weeks

mtnvirology@mtnstopshiv.org

Questions?

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