



Statistical Center for
HIV/AIDS Research & Prevention
SCHARP

DATA SUMMARY REPORT

ENROLLMENT, RETENTION, PROCEDURE COMPLETION, DATA MANAGEMENT QUALITY

MTN 014

February 10, 2015

**MTN 014 - A Phase I Crossover Trial Evaluating the Pharmacokinetics of Tenofovir
Reduced-Glycerin 1% Gel in the Rectal and Vaginal Compartments in Women
Data as of February 9, 2015**

Accrual Summary by Site

Site	Activation Date	First Enrollment Date	Last Enrollment Date¹	Duration of Accrual² (weeks)	Total Screened	Total Enrolled	Enrollment Target	Screen/Enroll	Average Enrolled per Week	Percent Enrolled	Percent Accrual Duration³
1. Bronx - Lebanon	04APR2014	19MAY2014	10OCT2014	38.1	20	14	14	1.4	0.4	100.0%	Completed

¹ Date of most recent enrollment as of February 9, 2015.

² Duration of accrual based on first enrollment date.

³ This is the percent of time that has elapsed from the first enrollment to the expected duration of accrual per protocol. For example, if the report is run on May 31, 2014, the site's first enrollment is on January 1, 2014 and the expected duration of accrual is 6 months, then the Percent Accrual Duration = 83.3%.

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Cumulative Percent Retention by Site

	Total Enrolled	# Completed Visits	# Expected Visits	Retention Rate
Bronx - Lebanon	14	386	419	92.1%

¹ This report includes data received and entered at SCHARP through this date.

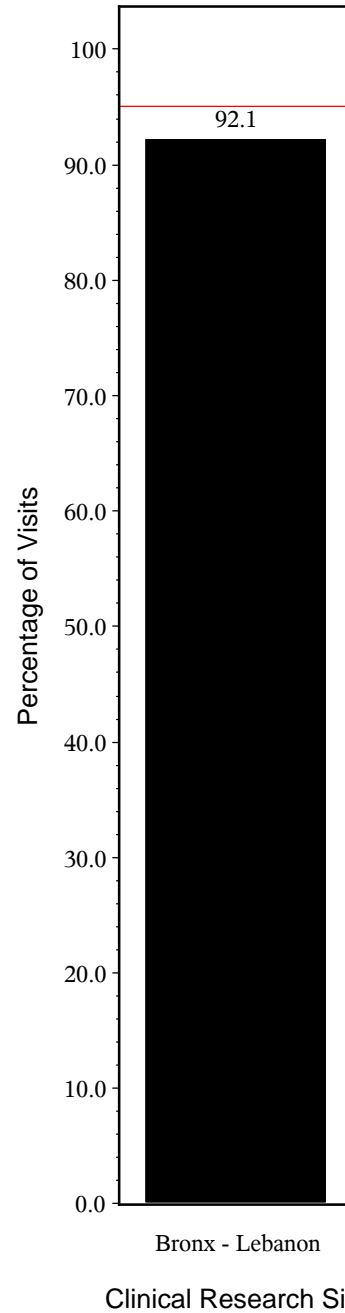
² The measures in this report summarize retention over all expected visits.

A visit is considered expected only once the participant's visit window has closed.

A visit is considered completed once the Visit Summary form is received and entered at SCHARP.

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Cumulative Percent Retention by Site



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Visit Adherence: Completion of Procedures During Follow-up¹ Visits

	1. Bronx Lebanon
Participants Enrolled	14
1. Pelvic Examination Required and Expected	51/51 (100%)
2. Perianal Examination Required and Expected	51/51 (100%)
3. Digital Rectal Examination Required and Expected	51/51 (100%)
4. Qualitative hCG Required and Expected	50/51 (98%)
5. HIV-1 Serology Required and Expected	23/23 (100%)
6. PBMC for PK Required and Expected	37/37 (100%)
7. Plasma for PK Required and Expected	37/37 (100%)
8. Plasma Archive Required and Expected	14/14 (100%)
9. Vaginal Swab for Biomarkers Required and Expected	51/51 (100%)
10. Endocervical Swab for Biomarkers Required and Expected	51/51 (100%)
11. Vaginal Swab for PK Required and Expected	37/37 (100%)
12. Cervicovaginal Lavage Required and Expected	37/37 (100%)
13. Cervical Cytobrush for PK Required and Expected	27/27 (100%)
14. Vaginal Biopsies for PK Required and Expected	26/27 (96%)
15. Vaginal Biopsies for Gene Expression Required and Expected	26/27 (96%)
16. Vaginal Smear for Gram Stain Required and Expected	51/51 (100%)
17. Vaginal pH Required and Expected	51/51 (100%)
18. Rectal Sponge for PK Required and Expected	37/37 (100%)
19. Rectal Sponge for PD and Biomarkers Required and Expected	51/51 (100%)
20. Rectal Biopsies for PK Required and Expected	26/27 (96%)
21. Rectal Biopsies for Gene Expression Microarray Required and Expected	26/27 (96%)
22. Rectal Biopsy for Histology Required and Expected	26/27 (96%)
23. Rectal Biopsy for Proteomics Required and Expected	26/27 (96%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit Case Report Form (CRF), the procedures for that visit will not be included as expected.

**MTN-014 A Phase I Crossover Trial Evaluating the Pharmacokinetics of Tenofovir
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**DATA MANAGEMENT QUALITY REPORT
Cumulative: Study Start through January 2015**

Site	Total Records	Total QCs	QC Rate Per 100 Records (Goal <5)	% QCs Resolved	%CRF Pages Received Within 7 days (Goal ≥ 95%)	Mean Days to Fax in AE
1. Bronx - Lebanon	1665	144	8.6	100%	99%	1.5

DEFINITION OF TERMS

Total Records: Total number of CRF records submitted to SCHARP DataFax (via fax or EDC) in the reporting time period. For CRFs submitted multiple times (via refaxes and EDC), the most recent CRF record submitted (using the record creation date) is included.

Total QCs: Total number of Quality Control records (QCs) created in the reporting time period that have appeared on QC Reports (sent to sites or accessed via iDataFax.) This does not include "missing page", "overdue visit", or "fax noise" QCs.

QC Rate Per 100 Records: This is the rate of QCs per 100 records. Obtained by dividing Total QCs by Total Records, and multiplying by 100.

% QCs Resolved: The percentage of Total QCs that have been resolved. Obtained by dividing the number of resolved QCs by Total QCs. % QCs Resolved is expected to be close to 100% for the cumulative reporting time period, but may be significantly less than 100% for the monthly reporting time period due to the scheduling/access of the QC Reports.

% CRF Records Faxed within 5 Days: The percentage of CRF records faxed to SCHARP within 5 days of the visit date. For CRFs faxed in multiple times, only the initial CRF record faxed in contributes to this metric. CRF records submitted via EDC do not contribute to this metric.

Mean Days to Fax in AE: Mean number of days for the site to complete the AE CRF and fax to SCHARP. Days to Fax in AE is the difference between the AE Reported to Site Date and the DataFax fax date stamp, in number of days. AE CRF records with a fax date within the reporting time period are included. For CRFs faxed in multiple times, only the initial CRF record faxed in contributes to this metric. CRF records submitted via EDC do not contribute to this metric.

**MTN-014 A Phase I Crossover Trial Evaluating the Pharmacokinetics of Tenofovir
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**DATA MANAGEMENT QUALITY REPORT
Previous Month: January 2015**

Site	Total Records	Total QCs	QC Rate Per 100 Records (Goal < 5)		%CRF Pages Received Within 7 days (Goal ≥ 95%)	Mean Days to Fax in AE
1. Bronx - Lebanon	0	0	.		.	.

DEFINITION OF TERMS

Total Records: Total number of CRF records submitted to SCHARP DataFax (via fax or EDC) in the reporting time period. For CRFs submitted multiple times (via refaxes and EDC), the most recent CRF record submitted (using the record creation date) is included.

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