

**MTN004: Phase I Study of the Safety and Acceptability of 3% w/w SPL7013 Gel (VivaGel)  
Applied Vaginally in Sexually Active Young Women By Site  
Visit Adherence: Completion of Procedures During Follow-Up\*  
Analysis Date: 23JAN10**

	<b>Total</b>	<b>Tampa, FL</b>	<b>San Juan, PR</b>	<b>Pittsburgh, PA</b>
Participant–Visits Where Pelvic Exams are Required and Expected	183	87	60	36
Naked Eye, Speculum, and Bimanual Exam				
Not Completed	1( 1%)	0	0	1( 3%)
Completed	182( 99%)	87( 100%)	60( 100%)	35( 97%)
Vaginal Gram Stain Smear Collected				
Not Completed	1( 1%)	0	0	1( 3%)
Completed	182( 99%)	87( 100%)	60( 100%)	35( 97%)
Cervical Swabs Collected				
Not Completed	1( 1%)	0	0	1( 3%)
Completed	182( 99%)	87( 100%)	60( 100%)	35( 97%)
Vaginal Swab Collected				
Not Completed	1( 1%)	0	0	1( 3%)
Completed	182( 99%)	87( 100%)	60( 100%)	35( 97%)
Participant–Visits Where Pregnancy Tests are Required and Expected	186	88	61	37
Not Completed	3( 2%)	1( 1%)	1( 2%)	1( 3%)
Completed	183( 98%)	87( 99%)	60( 98%)	36( 97%)
Participant–Visits Where Safety Lab Tests are Required and Expected	122	58	40	24
Completed	98( 80%)	58( 100%)	40( 100%)	0
Partially Completed	24( 20%)	0	0	24( 100%)
Participant–Visits Where Archival of Plasma for PK (SPL7013) is Required and Expected	61	29	20	12
Completed	61( 100%)	29( 100%)	20( 100%)	12( 100%)
Participant–Visits Where Completion of CASI is Required and Expected	61	29	20	12
CASI Acceptability & Adherence Questionnaire				
Completed	61( 100%)	29( 100%)	20( 100%)	12( 100%)
CASI Study Burden Questionnaire				
Completed	61( 100%)	29( 100%)	20( 100%)	12( 100%)

\*Includes only 1, 2, 3–week and termination visit where appropriate.

DATASETS: SCHARP (mjh)–/trials/mtn/p004/reporting/progress/adherence/code/visit\_adherence\_adata.sas  
SOURCE: /trials/mtn/p004/reporting/progress/adherence/code/visit\_adherence\_table.sas  
OUTPUT: /trials/mtn/p004/reporting/progress/adherence/code/MTN004\_visit\_adherence\_table.pdf SAS Version 9.1(23JAN10/01:15)