Road to the Finish Line

VOICE Protocol Team Meeting
19 February 2012





	0	Task Name	Start	Finish		2012					
	100				4th Quarter	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarte
1		☐ Participant Follow-up	Mon 10/3/11	Mon 8/13/12	OCI INDA IDEC	oali reb war	Apr May Jun	our Aug Sep	OCI INOV DEC	Jan rep mar	Apr May 3
2	m.	Tenofovir tablet participants exit	Mon 10/3/11	Tue 1/31/12							
3	-	Gel participants exit	Mon 11/28/11	Fri 4/20/12			_				
4	H	Truvada tablets and placebo tablets participants	Wed 2/1/12		_						
		exit									
5		Last follow-up visit	Mon 8/13/12	Mon 8/13/12				*			
6		☐ Laboratory Sample Shipment	Mon 10/3/11	Mon 12/3/12	7						
7		☐ HSV Testing	Tue 1/31/12	Mon 12/3/12		~					
8		─ Baseline sample testing at BARC	Tue 1/31/12	Tue 5/1/12		-					
9	H	Shipping list sent to sites	Tue 1/31/12	Tue 2/7/12		an a					
10		Sites send shipment to BARC	Wed 2/8/12	Thu 3MM2			6 6 7 8 8 8 8 8 8 8 8 8 8 8 8				
11		Testing at BARC/Results sent to NL/SCHARP	Fri 3/2/12	Mon 4/16/12			-				
12	111	Results review/data cleaning	Tue 4/17/12	Tue 5MM2			&				
13		☐ Baseline-Hegative participants Exit samp	Tue 5/15/12	Mon 12/3/12			—				
14	-	Shipping list sent to sites	Tue 5/15/12	Fri 9/14/12							
15	==	Sites send shipment to Seattle	Tue 5/15/12	Mon 10/15/12			4		<u></u>		
16	•	Testing at Seattle/Results sent to NL/SCHARP	Mon 10/15/12	Thu 11/15/12							
17	111	Results review/data cleaning	Fri 11/16/12	Mon 12/3/12					*		
18		☐ PK Testing	Mon 10/3/11	Mon 12/3/12							
19		☐ Within Study Shipment	Tue 1/31/12	Mon 4/23/12		-					
20	-	Shipping list sent to sites	Tue 1/31/12	Fri 2/10/12		a					
21	-	Sites send shipment to JHU	Mon 3/5/12	Mon 3/5/12		1	<u> </u>				
22	•	Testing at JHU/Results sent to SCHARP	Mon 4/9/12	Mon 4/9/12			t				
23	=	Results review/data cleaning	Mon 4/23/12	Mon 4/23/12			Ť				
24		☐ End of Study Shipment	Tue 5/15/12	Mon 12/3/12			<u> </u>				
25		Shipping list sent to sites	Tue 5/15/12	Fri 9/14/12							
26	==	Sites send shipment to JHU	Tue 5/15/12	Mon 10/15/12			4		<u></u>		
27	H.	Testing at JHU/Results sent to SCHARP	Tue 10/16/12	Thu 11/15/12					(
28	-	Results review/data cleaning	Fri 11/16/12	Mon 12/3/12					*		
29		☐ HIV Testing	Mon 10/3/11	Fri 11/30/12							
30	1	Endpoint QA testing	Mon 10/3/11	Wed 10/31/12							
31	-	Resistance testing	Mon 1/2/12	Fri 11/30/12			1				3 3 3 3 3 4 4
32		///									
33		☐ Data Management	Mon 8/13/12	Fri 5/31/13				<u> </u>			-
34	-	Data clean-up	Mon 8/13/12	Fri 3/15/13							
35		Data lock	Wed 5M/13	Fri 5/31/13							-
36	-	Primary data analysis	Mon 11/26/12	Thu 2/21/13					t		
37	-	Study Results Meeting	Mon 12/3/12	Mon 12/3/12					*		
38		Results Dissemination	Mon 3/11/13	Fri 3/29/13					7.7	*	-

- □ Last follow-up visit 13 August 2012
- □ Results meeting 3 December 2012
- Results dissemination 1st Q2013

- Laboratory
 - HSV Testing
 - Baseline samples:
 - Shipped to BARC 1 March 2012
 - Results sent to NL/SCHARP 15 April 2012
 - Baseline-Negative Participants Exit samples:
 - Shipped to Seattle 15 October 2012
 - Results sent to NL/SCHARP 15 November 2012

- Laboratory
 - PK Testing
 - Within Study Shipment
 - Shipped to JHU 5 March 2012
 - Results sent to NL/SCHARP 9 April 2012
 - End of Study Shipment
 - Shipped to JHU 15 October 2012
 - Results sent to NL/SCHARP 15 November 2012

- Laboratory
 - HIV Testing
 - Endpoint QA testing 31 October 2012
 - Resistance testing 30 November 2012

- Data Management
 - Data clean-up Mid 1st Q2013
 - Data lock End 1st Q2013/early 2nd Q2013
 - Primary data analysis Early 1st Q2013

Questions

