Imbokodo – HVTN 705 Number of Study Volunteers by Country and Regulatory Requirements

Country	Total Enrolled in Study	Total in Case-Control[1]	Total in Pilot[2]	Regulatory Remarks (time estimate to complete)
Malawi	157	14	N/A	For use of specimens, institutional labs in which sample use will occur must be added by amendment to MTA (~6mo+)
Mozambique	45	3	N/A	For use of specimens and/or data, institutional labs in which sample or data use will occur must be added by amendment to MTA (~6mo+)
South Africa	1774	252	30	For use of specimens, institutional labs in which sample use will occur must be added by amendment to MTA (~2 mo)
Zambia	330	30	13	For use of specimens, regulators require a bi-lateral agreement between the institutional lab recipient and the clinical site providing specimens (~6mo+)
Zimbabwe	331	35	17	For use of specimens, regulators require a bi-lateral agreement between the institutional lab recipient and the clinical site providing specimens (~6mo+)
Totals	**2637**	**334**	**60**	

In addition to above country-specific requirements, studies that request specimens from any participating Imbokodo country will require:

- Export permit for shipment of specimens, all of which are stored at a repository in RSA (occurs after MTA execution and adds ~3mo+)
- IRB approval from the institutional lab recipient(s)

[1] The case control set consists of participants in the Per Protocol population vaccine arm of the study that acquired HIV ("cases") and participants matched by baseline demographics that did not acquire HIV throughout the study ("controls") in a 1:5 ratio. This set of participants was included in the primary immune correlates analysis.

[2] The pilot set includes selected Per Protocol participants that did not acquire HIV throughout the study and were in the vaccine arm (n=50) or placebo arm (n=10). Longitudinal samples from these participants were tested in a pilot study on a range of immunogenicity assays.

Imbokodo – HVTN 705 Study Schema

Group	N	Month 0	Month 3	Month 6	Month 12
1	1300	Ad26.Mos4.HIV	Ad26.Mos4.HIV	Ad26.Mos4.HIV + Clade C gp140 (250 mcg + adjuvant)[a]	Ad26.Mos4.HIV + Clade C gp140 (250 mcg + adjuvant)[a]
2	1300	Placebo	Placebo	Placebo + Placebo	Placebo + Placebo

[a] 250 mcg refers to total protein content (Clade C gp140). Sterile aluminum phosphate suspension will be used as adjuvant. Aluminum content will be 0.425 mg/0.5 mL dose.

Imbokodo - HVTN 705 Specimen Collection Details: Visits for both HIV-Uninfected and HIV-Infected Participants

			Sample Collected? (X = Yes; X*= limited quantity)				
Visit#	**Timepoint (Day/Wk/Mo)**	**Visit Description**	**Serum**	**PBMC**	**Mucosal†**	**Plasma**	**Whole blood**
2	D0/W0/M0	Baseline; pre-1st Ad26/Placebo prime	**X**	**X**	**X***	**X***	**X***
3	D84/W12/M3	2nd Ad26/Placebo vaccination				**X***	
4	D168/W24/M6	1st Ad26 + gp140/Placebo boost	**X***	**X***	**X***	**X***	**X***
5	D169	Innate immunity timepoint	**X***	**X***			**X***
6	D182-196/W26-28/M6.5-7	Peak immunity at 2wk post-1st boost	**X**	**X**		**X***	
7	D273/W39/M9	5th HIV diagnostic visit				**X***	
8	D364/W52/M12	2nd Ad26 + gp140/Placebo boost	**X**	**X**	**X***	**X***	
9	D378-394/W54-56/M12.5-13	Peak immunity at 2wk post-2nd boost	**X**	**X**		**X***	
10	D455/W65/M15	7th HIV diagnostic visit				**X***	
11	D546/W78/M18	8th HIV diagnostic visit; 6mo durability	**X**	**X**	**X***	**X***	
12	D637/W91/M21	9th HIV diagnostic visit				**X***	
13	D728/W104/M24	10th HIV diagnostic visit; 12mo durability	**X**	**X**	**X***	**X***	
14	D819/W117/M27	11th HIV diagnostic visit				**X***	
15	D910/W130/M30	12th HIV diagnostic visit	**X**	**X**	**X***	**X***	
16	D1001/W143/M33	13th HIV diagnostic visit				**X***	
17	D1092/W156/M36	14th HIV diagnostic visit; end of study	**X**	**X**	**X***	**X***	

† Mucosal specimens may include: one vaginal swab and cervicovaginal secretions collected by cervical cup. Cervicovaginal secretions are processed for storage into separate fluid phase and mucin specimens.

Imbokodo - HVTN 705 Specimen Collection Details: Extra Visits for HIV-Infected Participants

Visit#	Timepoint (Wk/Mo after Diagnosis)	Visit Description	Sample Collected? (X = Yes; X*= limited quantity)			
			Serum	PBMC	Mucosal	Plasma
#.X †	Varies by participant (within ~ 2-4 weeks post-diagnosis)	Confirmatory redraw visit for HIV diagnostics	**X**	**X***	**X***	**X***
31	W12/M3	12 Weeks post-HIV diagnosis (i.e., date of initial specimen draw that led to first Redraw Request)	**X**	**X***		**X**
32	W24/M6	24 weeks post-HIV diagnosis	**X**	**X***		**X**

† Visit #.X is a Redraw visit where # is a visit number for all participants. Confirmatory draw for HIV diagnostics will be collected at the Redraw visit, which should occur as soon as possible after a Redraw Request from the HIV diagnostics laboratory. Multiple subsequent Redraw visits may be necessary; only the EDTA blood specimen for HIV diagnostics, viral isolation/sequencing, and plasma storage will be collected at the subsequent Redraw visits.