

Table S2: G001 schedule of procedures.

Visit Number	2		3		4		5	6	7	7A	8	9	10			
Study Month	-2.5	-1	0							2			4	6	8 ¹	14
Study Week	-10	-4	0	0.5	1	2	3	4	8	9 ²	10 ²	11 ²	16	20	32	56
Study Day	-70	-28	0	D3	7	14	21	28	56	63	70	77	112	140	224	392
Visit Windows (Days)	-42 to +7		0	± 1	+3	± 3	± 3	± 3	± 7	-2 to +1	± 4	± 3	± 7	± 7	± 14	+28
Investigational Product/Placebo			X						X							
Leukapheresis		X									X					
FNA							X						X			
Telephone Contact					X	X									X	
Informed Consent/AOU	X															
HIV Risk Assessment	X														X	
HIV Risk Reduction Counseling	X														X	X
HIV-test and Counseling	X														X ⁴	X
Family Planning Counseling	X		X						X				X		X	
Social Impact Assessment															X	
Comprehensive Medical History	X															
Interim Medical History		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medications	X	X	X			X	X	X	X	X	X	X	X ⁵			
General Physical Exam	X														X	
Directed Physical Exam		X	X			X	X	X	X	X	X	X	X			X
Weight	X	X									X					
Height	X															
Vital Signs	X	X	X			X	X	X	X	X	X	X	X		X	X
Cervical & Axillary Lymph Nodes ⁶			X			X ⁷			X	X					X	
Local & Systemic Reactogenicity			X	X	X	X			X	X						
Adverse Events			X	X	X	X	X	X	X	X	X	X	X ⁵			
Serious Adverse Events and/or pIMD	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X ⁸
Screening labs ⁹	X															
Safety labs ¹⁰	X		X			X			X		X		X		X	
Urine dipstick	X		X						X				X		X	
Pregnancy test	X	X	X				X		X		X	X	X		X	
Serum binding antibody			X			X			X	X	X	X	X			
B-cell sorting (PBMCs)		X							X	X	X		X			
B-cell sorting (FNA)								X				X				
Ag-specific CD4 T cells (PBMCs)		X									X					
Plasmablasts									X							
Serum neutralization			X			X			X		X		X			

¹ Early Termination (ET): Procedures to be performed at ET are the same as Month 8, except for HIV end-of-study testing, HIV risk and social impact assessment (Month 14).

² Study days 63, 70 and 77 must be counted from 7, 14 and 21 days respectively from time of the 2nd vaccination.

³ The window for the first leukapheresis can occur any time after completing successful screening up to 3 weeks prior to the first vaccination. The preferred target is at least 4 weeks before first vaccination.

⁴ If HIV infected, conduct ET visit, and see SOM for details.

⁵ New adverse events and concomitant medications collected only through Day 28 after second vaccination.

⁶ At each vaccination visit and during the reactogenicity period, an assessment of cervical and axillary lymph nodes is performed. If there are findings, continue to assess at later visits until resolved.

⁷ After the first vaccination, cervical and axillary lymph nodes will be assessed at the next clinic visit.

⁸ Follow-up for SAEs or potential immune-mediated diseases (pIMDs) with additional clinical follow-up, if indicated.

⁹ Screening labs include testing for hepatitis B, hepatitis C, syphilis, HIV testing and safety labs.

¹⁰ Safety labs include complete blood count with automated differential, platelet count, ALT, AST and creatinine.