DESMOND TUTU HEALTH FOUNDATION

DESMOND TUTU HIV CENTRE
UNIVERSITY OF CAPE TOWN

IAS Webinar 26March2026

Clinical Trials using Novel Germline Targeting Vaccine Strategies:

The BRILLIANT 011 Trial, B002 & DESIIGN001/IAVI G004

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BRILLIANT Consortium: launched in 2024, abruptly suspended in January 2025

A Consortium of 7 African Countries to develop and test an HIV vaccine in Africa

Trials & Projects Halted by USAID Funding Suspension

Project	Product(s)	Type	Country(ries)	# of participants
MATRIX	TAF/EVG Fast-dissolving insert	MATRIX-001 Phase 1 safety and acceptability	Kenya, South Africa, USA	60
	One month dapivirine vaginal film	MATRIX-002 Safety, acceptability, usability of placebo	Kenya, South Africa, USA, Zimbabwe	100
	Non-ARV nonhormonal contraceptive multipurpose vaginal ring	MATRIX-003 Safety, acceptability, usability of placebo	South Africa, USA, Zimbabwe	100
	Injectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC	Cohort study of safety in mothers and babies exposed to ARV-based prevention	Kenya, Lesotho, Zimbabwe	500-800
	One-month dapivirine vaginal film plus levonorgestrel (LNG)	Preclinical study	USA	Preclinical
BRILLIANT CONSORTIUM	BG505 GT1.1 and 426c.Mod.Core-C4b	B-001 Phase 1 clinical trial	Kenya, South Africa, Uganda	48
	Polyvalent HIV-SET saMRNA vaccine clinical program	Pre-clinical and clinical trials	Multiple African countries	Exploratory
	CAP 256 based mRNA vaccine candidates incl Africa-based mRNA manufacturing	Development program	Multiple African countries	Exploratory
	Multiple founder virus-based vaccines	Exploratory program	Multiple African countries	Exploratory
	Tech-transfer activities in Uganda with SOSIP trimers	Technology transfer	Uganda	Exploratory
ADVANCE	Mosaic Trimers: MOS1SIP, MOS2SIP, M3SIP8 and MPLA	Vaccine	Rwanda, Zambia	40
	Multisite Adolescent Girls and Young Women study	MAGY Epidemiological study	Uganda, Zambia, Kenya, South Africa	1,210
MOSAIC	Injectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC	CATALYST Implementation Science Study	Kenya, Lesotho, South Africa, Uganda, Zimbabwe	7,500
	Injectable CAB, Dapivirine Vaginal Ring	Policy and progammatic support, including user-centered research and technical assistance	Bostwana, Eswatini, Kenya, Lesotho, Namibia, South Africa, Uganda, Zambia, Zimbabwe	Community-based
	Dapivirine Vaginal Ring, Oral TDF/FTC	Increasing PrEP Options for Women in Eswatini	Eswatini	400
CASPR	PrEP, vaccines and multipurpose technologies	Research translation and preparedness, policy support and advocacy to support prevention research	Kenya, Lesotho, Malawi, Nigeria, South Africa, Uganda, Zambia, Zimbabwe	Community-based

AVAC
Advocacy. Access. Equity.

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saMRC advancinglife

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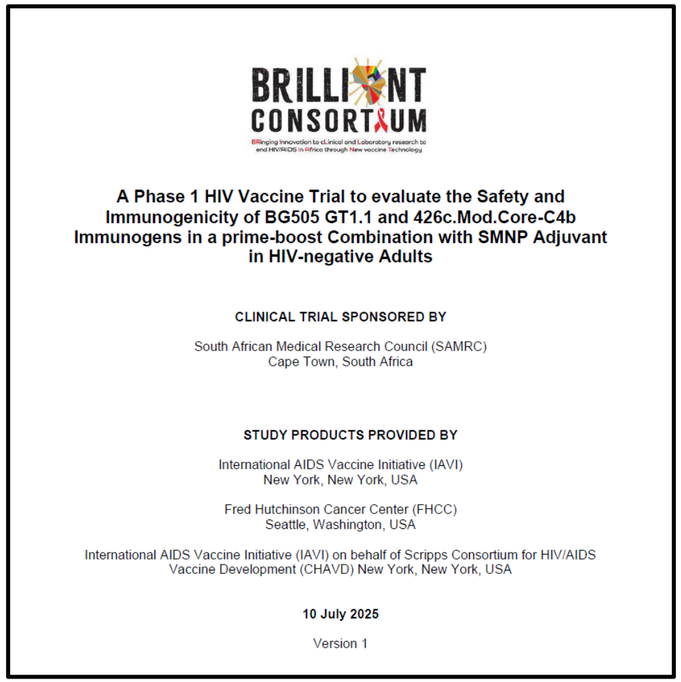
BRILLIANT-011

- A Phase 1 HIV Vaccine Trial to evaluate the Safety and Immunogenicity of BG505 GT1.1 and 426c.Mod.Core C4b Immunogens in a prime-boost Combination with SMNP Adjuvant in HIV-negative Adults
- Goal is To evaluate the ability of a novel combination of two germline-targeting immunogens BG505 GT1.1 and 426c.Mod.Core-C4b with SMNP to trigger precursors of bNAbs.



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A Phase 1 HIV Vaccine Trial to evaluate the Safety and Immunogenicity of BG505 GT1.1 and 426c.Mod.Core-C4b Immunogens in a prime-boost Combination with SMNP Adjuvant in HIV-negative Adults

CLINICAL TRIAL SPONSORED BY

South African Medical Research Council (SAMRC)
Cape Town, South Africa

STUDY PRODUCTS PROVIDED BY

International AIDS Vaccine Initiative (IAVI)
New York, New York, USA

Fred Hutchinson Cancer Center (FHCC)
Seattle, Washington, USA

International AIDS Vaccine Initiative (IAVI) on behalf of Scripps Consortium for HIV/AIDS Vaccine Development (CHAVD) New York, New York, USA

10 July 2025

Version 1

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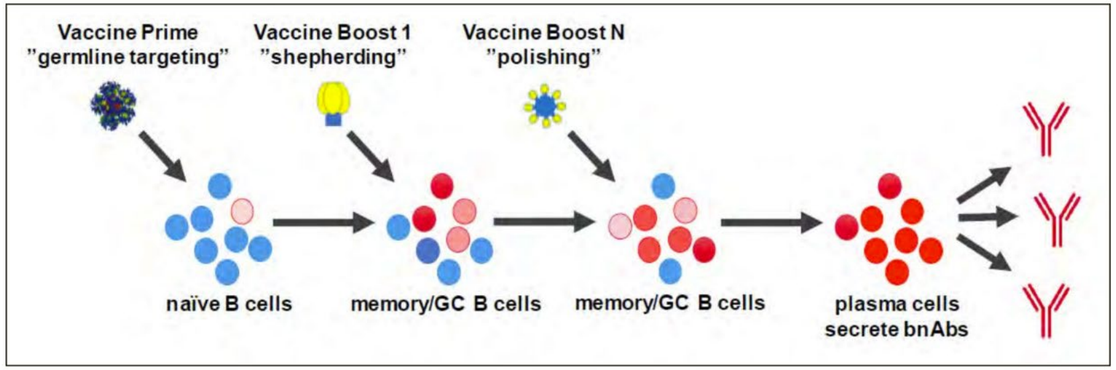
Background

- Traditional vector-based HIV vaccine approaches have only been partially successful, mainly eliciting non-neutralizing antibodies (RV144, Uhambo, Imbokodo, and other trials).
- Broadly neutralizing antibodies (bNAbs) that neutralize circulating virus are likely required to prevent HIV infections (e.g. AMP trials).
- A promising approach: Selecting Env immunogens with high affinity to the B cell receptor of the unmutated common ancestor B cell or naïve B cells with the germline genes of specific bNAb lineages
- Two germline targeting immunogens are 426c.Mod.Core-C4b (binds VRC01-class CD4bs-directed bNAb precursors) and BG505 GT1.1 (binds precursors of both CD4bs-directed and V1V2-directed bNAbs)



Trials using BG505 GT1.1 and 426c.Mod.Core

BILL & MELINDA GATES foundation

IAVI C101 - Study design

IAVI International AIDS Vaccine Initiative

		Months		
Group	**N[1)]**	0	2	6
A	**20**	30 µg BG505 GT1.1, AS01b	30 µg BG505 GT1.1, AS01b	30 µg BG505 GT1.1, AS01b
	4	placebo	placebo	placebo
B	**20**	300 µg BG505 GT1.1, AS01b	300 µg BG505 GT1.1, AS01b	300 µg BG505 GT1.1, AS01b
	4	placebo	placebo	placebo
TOTAL	**48**			

HIV VACCINE TRIALS NETWORK

PROTOCOL

HVTN 301

A phase 1 clinical trial to evaluate the safety and immunogenicity of priming regimens of 426c.Mod.Core-C4b and optional boost regimen with HIV Trimer BG505 SOSIP.GT1.1 gp140, both adjuvanted with 3M-052-AF + Alum in healthy, adult participants without HIV

Table 1-1 Schema

		Prime	Boost	Optional BG505 SOSIP.GT1.1 gp140 Boost Regimen**	
Group	**N**	**Month 0**	**Month 3 (groups 1-3) Month 3.75 (groups 4-6)**	**≥Month 15**	**≥Month 18 (3 months later)**
Bolus Delivery Arm					
1	12	426c.Mod.Core-C4b *Bolus* 100 mcg	426c.Mod.Core-C4b *Bolus* 30 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg
2	12	426c.Mod.Core-C4b *Bolus* 100 mcg	426c.Mod.Core-C4b *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg
3	2	*Bolus* Placebo	*Bolus* Placebo	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg
Fractionated Delivery Arm					
4	12	426c.Mod.Core-C4b *Fractionated delivery* 100 mcg total (details below)	426c.Mod.Core-C4b *Bolus* 30 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg
5	12	426c.Mod.Core-C4b *Fractionated delivery* 100 mcg total (details below)	426c.Mod.Core-C4b *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg
6	2	*Fractionated delivery* Placebo (details below)	*Bolus* Placebo	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg	BG505 SOSIP.GT1.1 gp140 *Bolus* 300 mcg
Total	**52 +**				

426c.Mod.Core-C4b and BG505 SOSIP.GT1.1 gp140 will be mixed with 3M-052-AF (5 mcg) + Alum (500 mcg) adjuvant and administered IM via needle and syringe.

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The journey from Brilliant-001→Brilliant-011

BRILLIANT-001 original vaccination schedule

Group	N	Prime (Day 0)	Prime (Week 8)	Boost (Week 24)	Boost (Week 40)
1	10	BG505 GT1.1 + 3M-052-AF/ Alum	BG505 GT1.1 + 3M-052-AF/ Alum	BG505 GT1.1 + 3M-052-AF/ Alum	BG505 GT1.1 + 3M-052-AF/ Alum
2	10	426c.Mod.Core-C4b + 3M-052-AF/ Alum	426c.Mod.Core-C4b + 3M-052-AF/ Alum	BG505 GT1.1 + 3M-052-AF/ Alum	BG505 GT1.1 + 3M-052-AF/ Alum
3	10	426c.Mod.Core-C4b +3M-052-AF/ Alum	426c.Mod.Core-C4b + 3M-052-AF/ Alum	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum*	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum *
4	10	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum*	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum*	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum*	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum*
2 per arm	8	Placebo	Placebo	Placebo	Placebo

BG505 GT1.1 dose is 300mcg for prime and boost. Prime dose for 426c.Mod.Core-C4b is 100mcg and the boost dose is 30mcg.

*For group 3 boost and group 4 the adjuvant dose admixed with the immunogen will be adjusted to 2.5mcg for 3M-052-AF and 250mcg for Alum.

Table 1.1 BRILLIANT-001 Study Schema

No.	Prime 1 (Day 0)	Prime 2 (Week 8)	Boost 1 (Week 24)	Boost 2 (Week 40)
16/4 Active/Placebo	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum	BG505 GT1.1 + 426c.Mod.Core-C4b + 3M-052-AF/ Alum

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BRILLIANT-011: A novel Cocktail Concept

Table 1.1 BRILLIANT-011 Study Schema

No.	Prime 1 **(Day 0)**	Prime 2 **(Week 8)**	Boost **(Week 24)**
16 Active	BG505 GT1.1 + SMNP	BG505 GT1.1 + SMNP	BG505 GT1.1 + SMNP
	426c.Mod.Core-C4b + SMNP	426c.Mod.Core-C4b + SMNP	426c.Mod.Core-C4b + SMNP
4 Placebo	Placebo	Placebo	Placebo
	Placebo	Placebo	Placebo

Optimal Dosing:
BG505 GT1.1 dose is 300mcg for prime and boost.
Prime dose for 426c.Mod.Core-C4b is 100mcg and the boost dose is 30mcg.
SMNP adjuvant dose is 100mcg for prime and boost. Each immunogen is admixed with 50mcg of SMNP

Brilliant-011 Study Products

- **426c.Mod.Core-C4b** binds VRC01-class CD4bs-directed bNAb precursors (**Leo Stamatatos – Fred Hutch**)
- **BG505 GT1.1** binds precursors of both CD4bs-directed and V1V2-directed bNAb precursors (**Rogier Sanders – University of Amsterdam**)
- **S**aponin/**M**onophosphoryl lipid A **N**ano**p**articles **(SMNP) adjuvant** (self-assembling nanoparticle adjuvant combining saponin, cholesterol, DPPC, and MPLA (TLR4 agonist) into ~40nm honeycomb structures that enhance immune responses (**IAVI** on behalf of **Scripps Consortium** for HIV/AIDS Vaccine Development (CHAVD))

Primary Objectives

- Determine the **safety and tolerability** of 426c.Mod.Core-C4b and BG505 GT1.1 immunogens administered as a cocktail with SMNP adjuvant in HIV negative adults.
- Determine the quality and quantity of **Env-specific binding antibodies** (Abs) elicited by vaccination with 426c.Mod.Core-C4b and BG505 GT1.1 immunogens in combination with SMNP adjuvant.
- Evaluate and compare the **neutralizing antibody** (nAb) responses after immunization with 426c.Mod.Core-C4b and BG505 GT1.1 in combination with SMNP adjuvant.

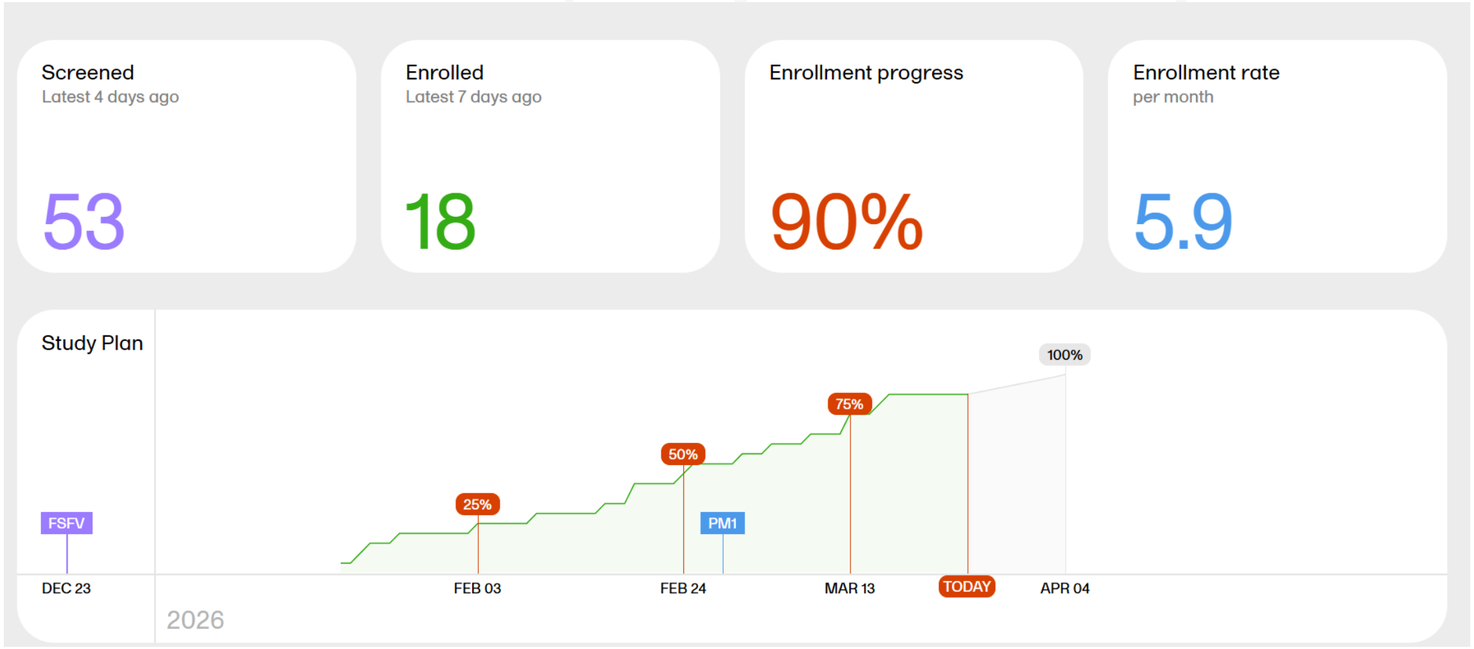
Exploratory Objectives

- Determine the expansion of CD4 binding site (CD4-bs) reactive B cells including VRC01 class B cells following immunization with 426c.Mod.Core-C4b and BG505 GT1.1 immunogens in at two weeks after the week 24 vaccination.
- Evaluate immune responses elicited by 426c.Mod.Core-C4b and BG505 GT1.1 immunogens.
- To conduct analyses related to furthering the understanding of HIV, immunology and vaccines, including but not exclusive to B cell repertoire analysis, antibody function and analyses of T-cell responses.

Study Population and Enrolment Update

Population

- 20 healthy, HIV-1 negative volunteers aged 18 to 40 years
- 16 vaccinees, 4 placebo recipients



Clinical Research Site

- Groote Schuur - J52 Site, Desmond Tutu Health Foundation, Cape Town, South Africa

- Reasons for screen failures: failed leukapheresis, HIV risk status/HIV infection, lab results not meeting inclusion

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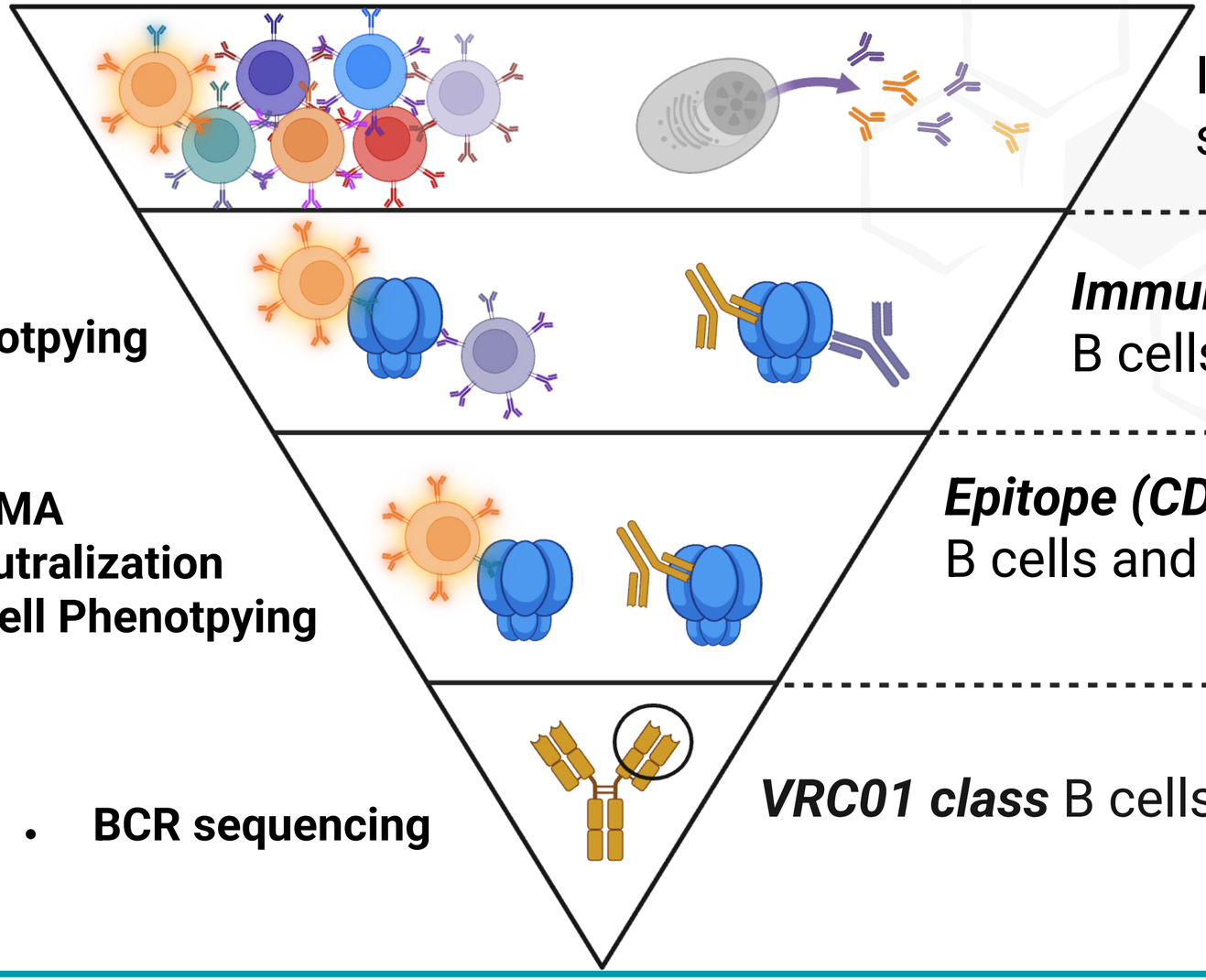
Early Safety Data

18 enrolments (20 Jan - 20 Mar 2026)

- Mild solicited Aes reported
- Mild-moderate unsolicited Aes reported
- Mild leukapheresis procedure related events
- No SAEs/EAEs or AESIs, pregnancies or seroconversions

Measuring Immunogenicity in B-011 (B cell analytics pipeline)



IgG⁺ B cells and serum antibodies

- **BAMA**
- **B cell Phenotpying**

Immunogen specific B cells and antibodies?

- **BAMA**
- **Neutralization**
- **B cell Phenotpying**

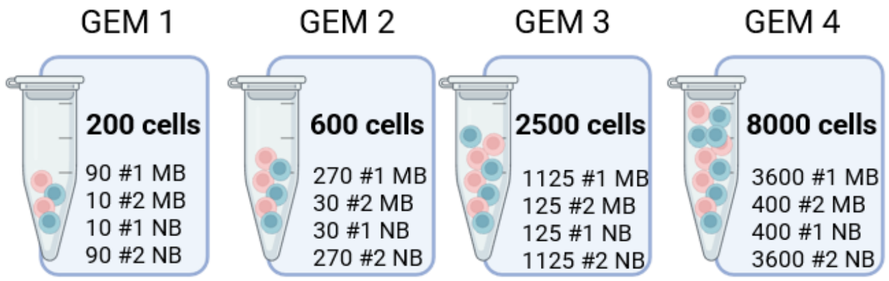
Epitope (CD4bs) specific B cells and antibodies?

- **BCR sequencing**

VRC01 class B cells?

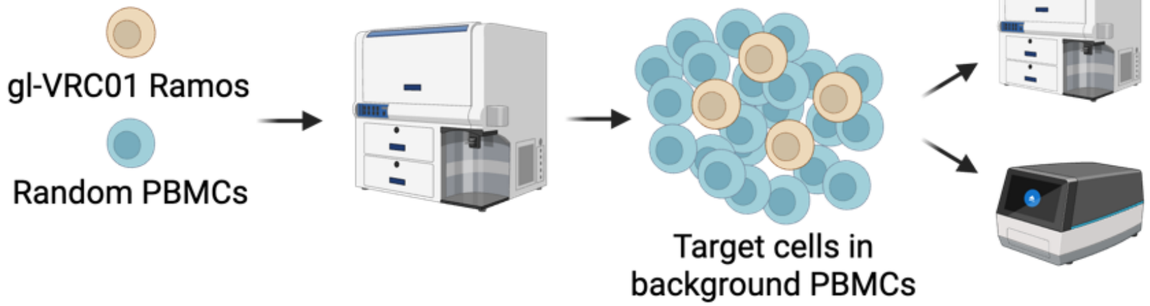
B-011 Preparatory Work Underway

Sensitivity Experiment
What are the lower limits of detection?



Assess:
1. Total cell recovery
2. Population ratios

Recovery Experiment
Can we detect antigen reactive B cells against background?



Assess :
Recovery of target antigen +ve cells

Assess:
Recovery of target BCR sequence

C101 Bridging Experiment
Can we replicate C101 results with out system?

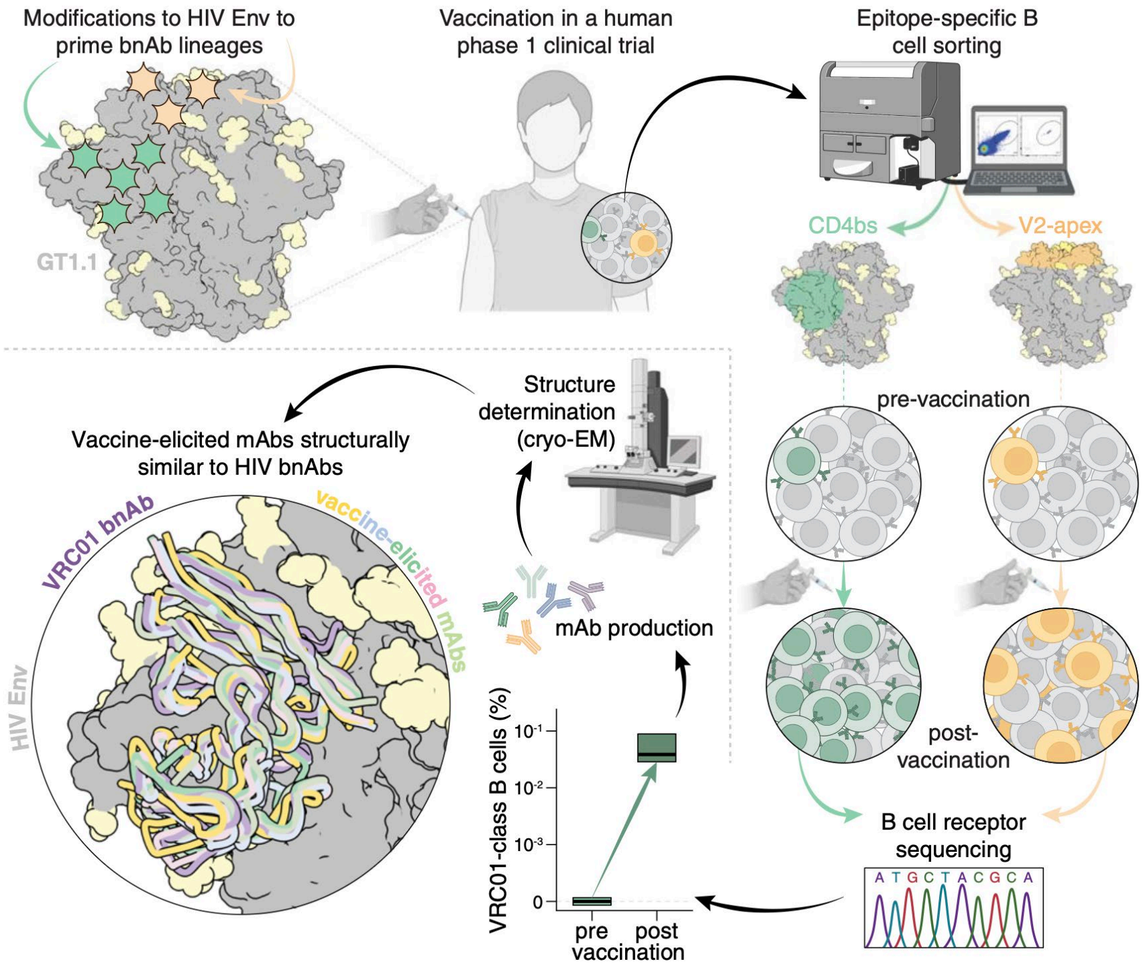
Assess:
1. Recovery of CD4bs directed B cells
2. Recovery of VRC01-class BCR sequences

Brilliant-011 Timelines

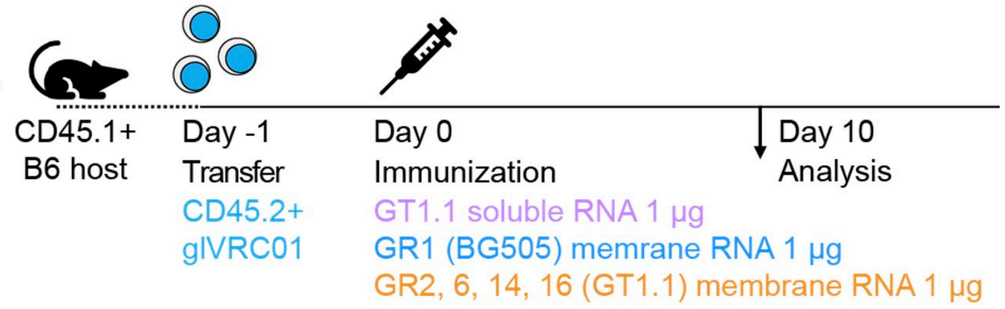
- Complete Enrollment by March 2026
- Final product administration September 2026
- Clinical Follow up complete by January 2027
- BAMA and neutralization assays during study
- B cell sequencing and T-cell work at end of study

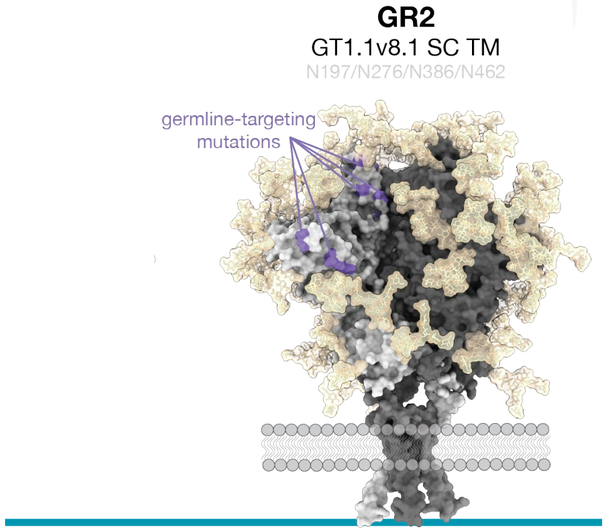
Background to BRILLIANT-002 Trial

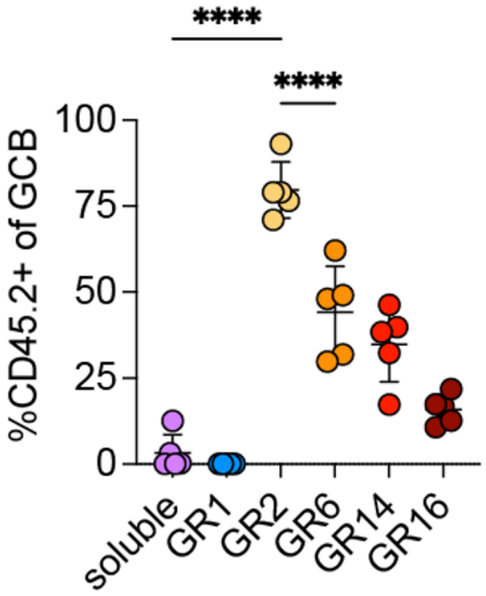
GT1.1 has shown promise in Phase 1 clinical trial (IAVI C101)



mRNA version of GT1.1 (GR2) idenitified as most promising version to be delivered as mRNA/LNP







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BRILLIANT-002 Trial Design

Title: A randomized, placebo-controlled Phase 1 Trial to evaluate the Safety and Immunogenicity of single versus two Dose GT1.1 (GR2) mRNA Immunogen Prime with GR22 and GR76 mRNA Boost Combinations in Adults living without HIV

Arm	Sample	Dose (mcg)	Interval	Month 0	Month 2	Month 4	Month 6	Month 10
1	6	10	Short	GR2	Placebo	GR22	GR76	
2a	6	10	Short	GR2	GR2	GR22	GR76	
2b	6	10	Long	GR2	GR2		GR22	GR76
3	6	30	Short	GR2	Placebo	GR22	GR76	
4a	6	30	Short	GR2	GR2	GR22	GR76	
4b	6	30	Long	GR2	GR2		GR22	GR76
5	6	90	Short	GR2	Placebo	GR22	GR76	
6a	6	90	Short	GR2	GR2	GR22	GR76	
6b	6	90	Long	GR2	GR2		GR22	GR76
7a	3	Placebo	Short	Placebo	Placebo	Placebo	Placebo	
7b	3	Placebo	Long	Placebo	Placebo		Placebo	Placebo
Total	60							

60 participants will be randomized and enrolled into 11 arms to assess a single vs two doses for GR2 priming, different dose levels, and a short versus long vaccination schedule.

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Study population and research sites

Participants

- 60 healthy, HIV-1 negative volunteers aged 18 to 40 years; 54 vaccinees, 6 placebo recipients

Study sites

- 3 clinical research sites in South Africa: Desmond Tutu Health Foundation (DTHF) in Cape Town, Perinatal HIV Research Unit (PHRU) in Johannesburg, and Centre for the AIDS Programme of Research (CAPRISA) in Durban

Duration per participant

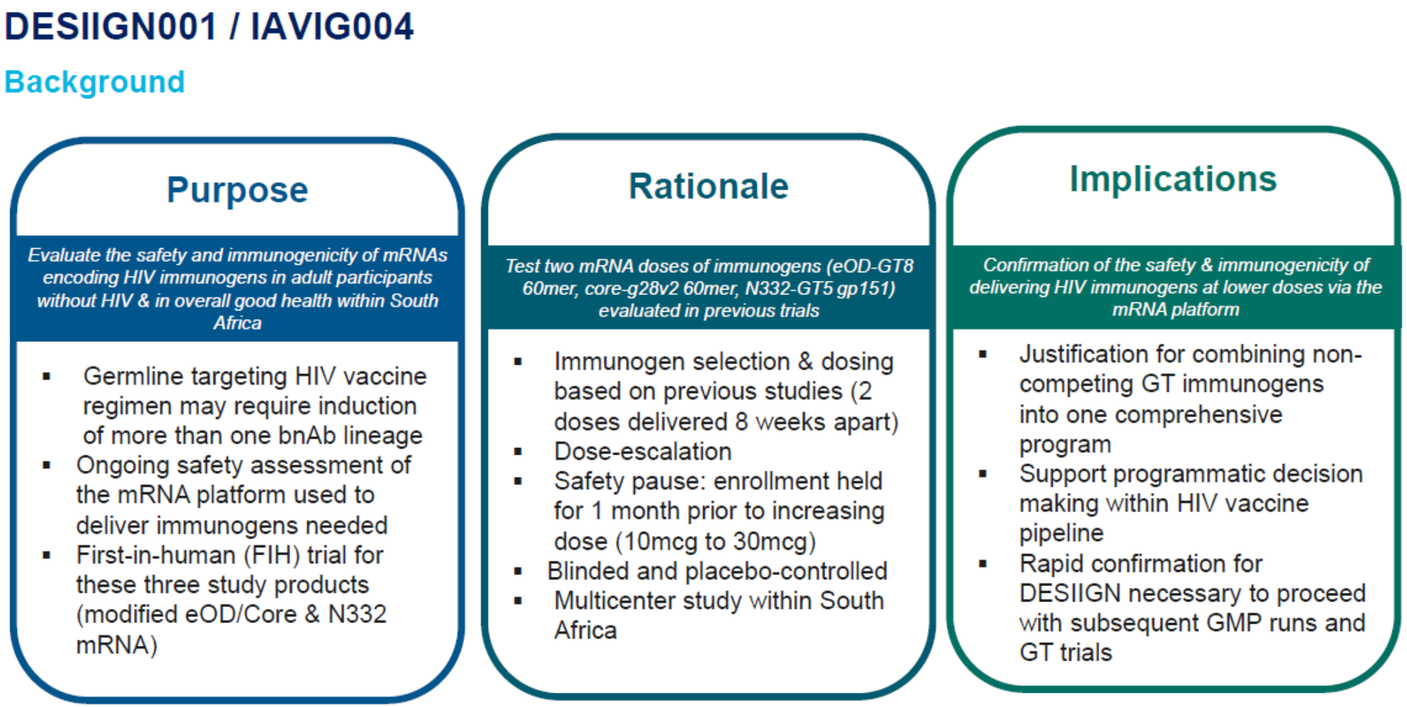
- Participants assigned to the short vaccination schedule will have 40 weeks of scheduled clinic visits. Those assigned to the long vaccination schedule will have 56 weeks of scheduled clinic visits.

Estimated total study duration

- 2.5 years (includes screening, enrolment period, follow-up and analyses).

Other trials using Novel Germline Targeting Approach: **DESIIGN001|IAVI G004**

- A Phase 1, Placebo-controlled, Blinded, Dose-escalation Study to Evaluate the Safety and Immunogenicity of mRNAs Encoding HIV Immunogens (eOD-GT8 60mer, core-g28v260mer, N332-GT5 gp151) in Adult Participants without HIV and in Overall Good Health in South Africa



Shepherding nascent bnAb responses towards breadth

A

Can eOD-GT8 elicit VRC01-like Ab response in humans?

B

Can eOD-GT8 induced B-cell responses be boosted?

C

Is mRNA-delivered eOD-GT8 60mer safe and effective for inducing and maturing VRC01-class responses in humans

D

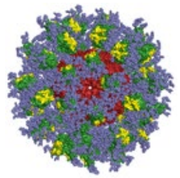
Are responses to eOD-GT8 similar across trial participant populations in The USA and Africa?

IAVI G001
Recombinant protein
eOD-GT8 60mer prime
US Populations

IAVI G002
mRNA expressed:
eOD-GT8 60mer prime,
Core-g28v2 60mer boost
US Populations

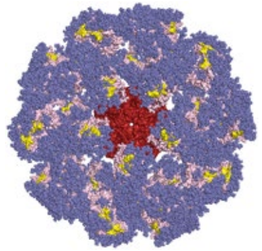
IAVI G003
mRNA expressed:
eOD-GT8 60mer prime
African Populations

IAVI G001



GT8 60mer

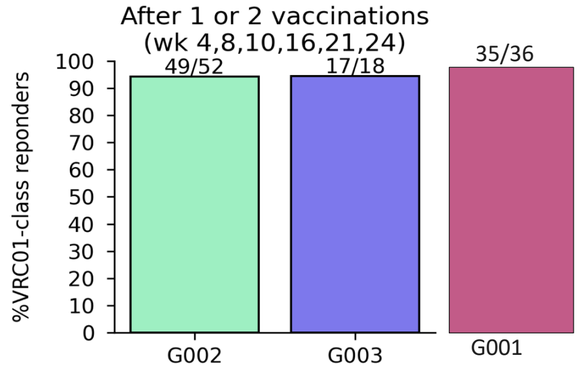
IAVI G002



core 60mer

IAVI G002
IAVI G003

IAVI G002
IAVI G003



Willis et al., Science 2025

DESIIGN001 / IAVI g004 study products

- eOD-GT8 60mer mRNA (mRNA-1645-eODGT8): eOD-GT8 60mer is a self-assembling nanoparticle composed of 60 subunits of the engineered HIV1 gp120 outer domain germline targeting version 8 (eOD-GT8) fused to an engineered form of a bacterial enzyme, Lumazine Synthase, through a 15amino acid Glycine-Serine linker. eOD-GT8
  - 60mer will be delivered using an mRNA lipid nanoparticle (LNP) platform. 0.5mL to be administered by intramuscular (IM) injection at doses of 10 or 30 mcg.
- core-g28v2 60mer mRNA (mRNA-1645-CoreG28v2): core-g28v2 60mer is a nanoparticle composed of 60 protein subunits of an engineered core-gp120 fused to an engineered form of a bacterial enzyme, Lumazine Synthase, through a 21-amino acid Glycine-Serine linker. Core-g28v2 60mer will be delivered using an mRNA-LNP platform.
  - 0.5mL to be administered by IM injection at doses of 10 or 30 mcg.
- N332-GT5 gp151 mRNA (mRNA-1645-N332GT5): N332-GT5 gp151 is an HIV envelope glycoprotein gp151 trimer based on BG505 SOSIP MD39 (clade A) trimer with “germline-targeting” mutations added that confer the ability to bind germline precursors of BG18 class B cells. N332-GT5 gp151 will be delivered using an mRNA-LNP platform.
  - 0.5mL to be administered by IM injection at doses of 10 or 30 mcg.
- Placebo (0.9% Sodium Chloride for injection)
  - 0.5mL to be administered by IM injection.

DESIIGN001/IAVI G004 Study design

- A multicenter, blinded, placebo-controlled, dose-escalation trial in participants without HIV and in overall good health, 18 to 55 years of age in South Africa.
- first-in-human (FIH) trial for the study products

Table 1-1 Schema

Cohort	Group	N	Dose	Week 0	Week 8
Part A: 10 mcg dose level					
1A	1	16	10 mcg	mRNA-1645-eODGT8	mRNA-1645-CoreG28v2
	2	8	—	Placebo	Placebo
2A	3	16	10 mcg	mRNA-1645-N332GT5	mRNA-1645-N332GT5
	4	8	—	Placebo	Placebo
Part B: 30 mcg dose level					
1B	5	16	30 mcg	mRNA-1645-eODGT8	mRNA-1645-CoreG28v2
	6	8	—	Placebo	Placebo
2B	7	16	30 mcg	mRNA-1645-N332GT5	mRNA-1645-N332GT5
	8	8	—	Placebo	Placebo
Total[1]: 96 (64 vaccinees, 32 placebo recipients)					

- 2:1 randomization ratio, active: placebo. 64 participants will receive active vaccine, and 32 will receive placebo.
- Enrollment in Part A: Cohorts 1A and 2A in Part A will be enrolled concurrently.
- Planned safety hold to proceed with dose escalation: After Part A is fully enrolled, there will be a planned safety hold to review all safety data from participants for one month following the final participant's first vaccination (week 0) in Part A. Enrollment in Part B will not proceed without the formal approval of the Protocol Safety Review Team (PSRT).
- Enrollment in Part B: Similar to enrollment in Part A, Cohorts 1B and 2B in Part B will be enrolled concurrently.

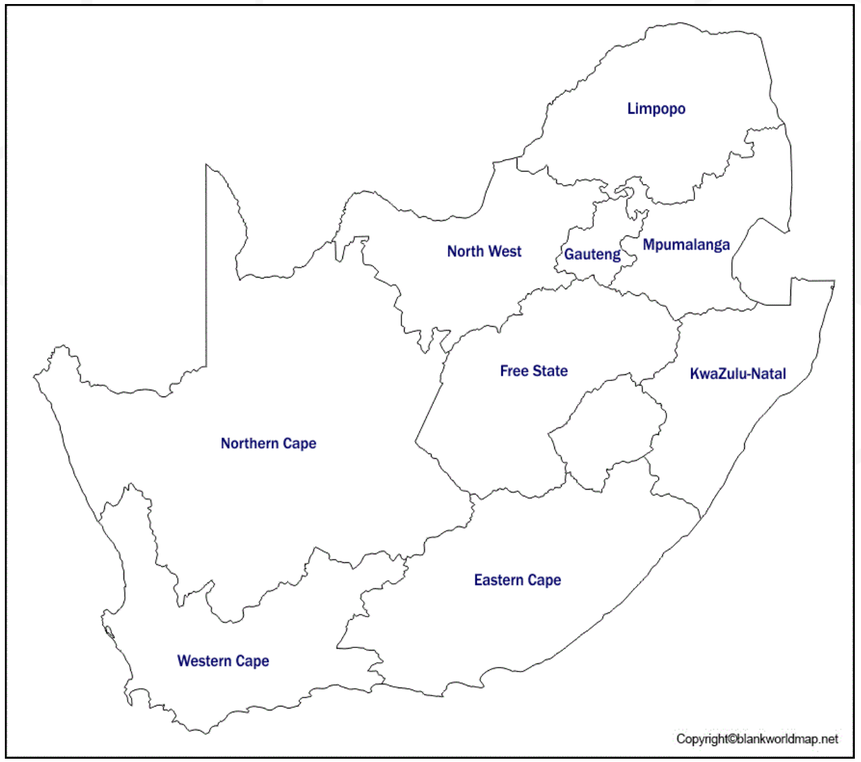
Desiign001/IAVI G004 Study Population and Study Sites

Participants

– 96 healthy, HIV-1 negative volunteers aged 18 to 55 years

- **Study sites**

– 6 clinical research sites in South Africa: Gauteng, KZN and Western Cape



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Conclusions

- The Brilliant programme is an African led programme for innovative vaccine design strategies to induce bNAbs
- The programme is centred around a stepwise approach to eliciting BNAbs
- Multiple studies underway (FIH) to evaluate safety and immunogenicity of these novel germline targeting strategies
- Results from these safety and immunogenicity trials will inform and catapult us into the next phase of vaccine trials in Africa

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