



# **THE TALE OF TWO STUDIES: EXECUTING HVTN 702 & HVTN 705**

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HIV VACCINE  
TRIALS NETWORK

Cent Gardes Conference HIV Vaccines 2019



CELEBRATING  
**50**  
YEARS



**UNAIDS HAS DECLARED THAT A 90%  
REDUCTION IN INCIDENCE FROM  
2010 IN EACH COUNTRY WOULD END  
THE AIDS EPIDEMIC AS A PUBLIC  
HEALTH THREAT**

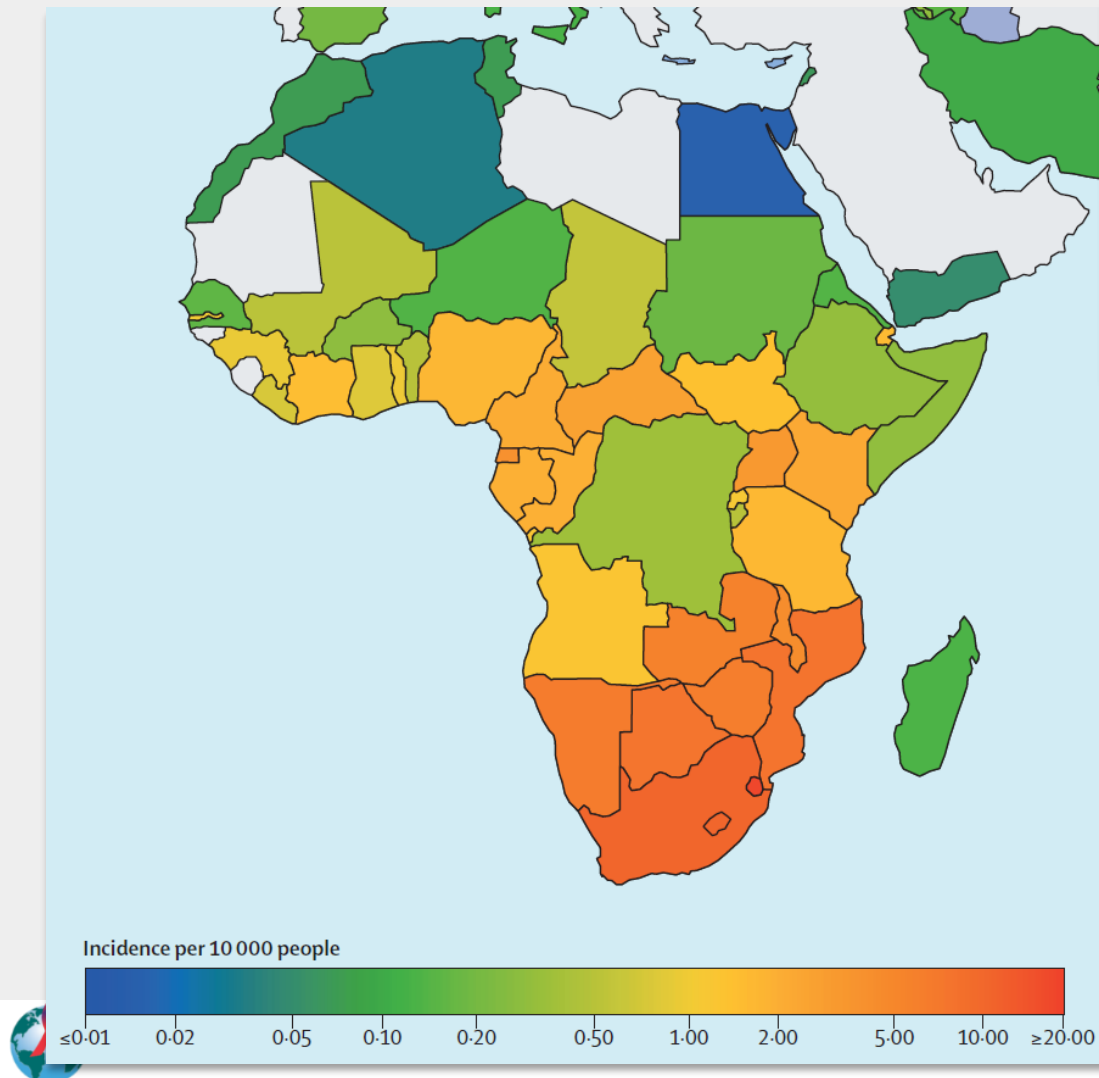


HIV VACCINE  
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# EPIDEMIC CONTROL: <1/10 000 PER YEAR



## Defining control of HIV epidemics

Alison P Galvani, Abhishek Pandey, Meagan C Fitzpatrick, Jan Medlock, Glenda E Gray

Although the HIV pandemic remains a global crisis, much progress has been made in implementing programmes to treat and prevent HIV infection. To guide prioritisation of efforts, the metric by which a country can declare its HIV epidemic as controlled has become increasingly relevant. Herein, we evaluate the merits of the four control criteria proposed by UNAIDS: percentage reduction in incidence over time; ratio of incidence to mortality; ratio of incidence to prevalence; and annual incidence. Using a transmission model to generate projections of demography, incidence, and mortality, we highlight potential pitfalls associated with each of the first three criteria. A definition of control based on annual incidence would provide clarity and consistency across settings.



Lancet HIV 2018; 5: e667-70

Published Online

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[http://dx.doi.org/10.1016/S2352-3018\(18\)30178-4](http://dx.doi.org/10.1016/S2352-3018(18)30178-4)

Center for Infectious Disease

Modeling and Analysis, Yale

School of Public Health,

New Haven, CT, USA

Concordant with WHO definition to define control for other diseases.

Temporal Milestones:

1. 1/1000 by 2030
2. 1/10 000 by 2035
3. RSA: 11.5/1000 (2018)
4. RSA: 1/1000 in 2030=91.3% drop



**THAT'S WHY WE NEED  
SOMETHING THAT IS  
DISRUPTIVE: HIV VACCINE**

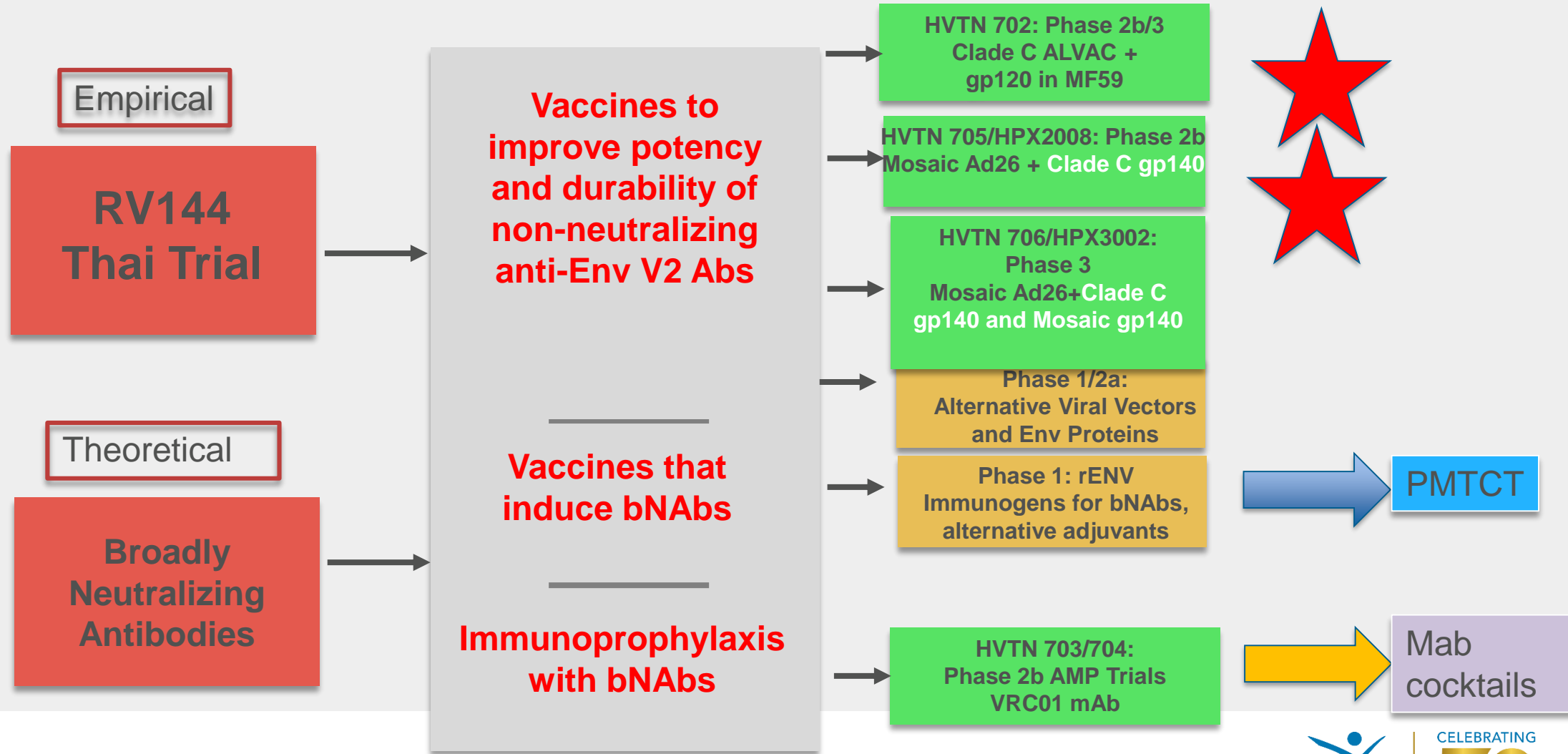


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# CURRENT NIH/HVTN HIV VACCINE STRATEGIES



# HVTN'S 3 PRONG STRATEGY IN THE FIELD

Clade C approach  
HVTN 702

Global vaccine approach  
HVTN 705/HPX2008 &  
706/HPX3002

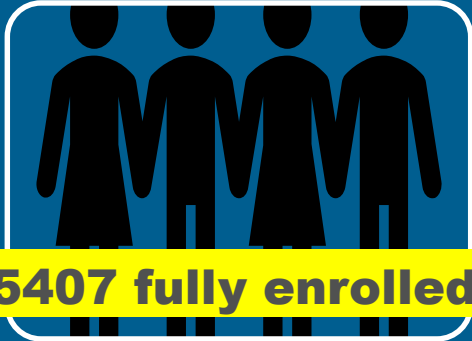
Neutralising antibody  
approach  
AMP/HVTN 703/4



HIV VACCINE  
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CELEBRATING  
**50**  
YEARS



## HVTN 702/UHAMBO (pox-protein heterologous prime boost)

- Evidence of modest efficacy in RV144
- Adapted to Clade C: met the go/no go criteria in HVTN 100
- Evaluated in RSA only

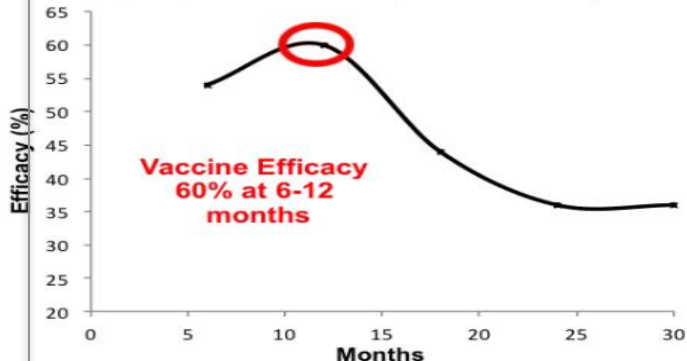


## HVTN 705/HPX2008/IMBOKODO (Ad26-Ad26/protein, heterologous double prime/double boost)

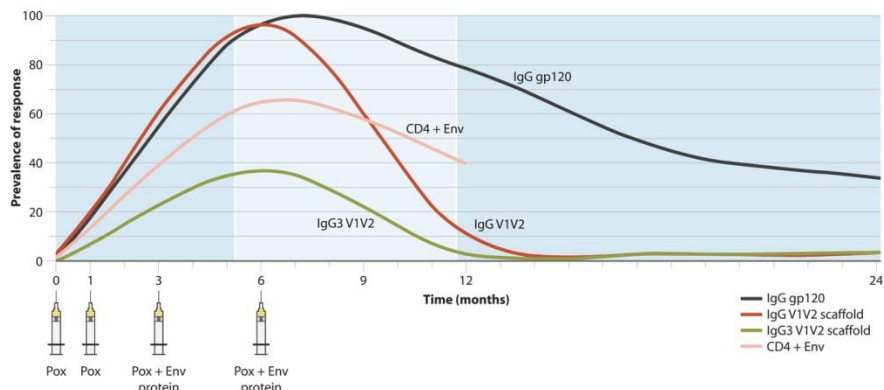
- Evidence of protection in NHP challenge model
- Advanced in POC after meeting go/no go criteria in TRAVERSE
- heterosexual women in SSA



# RATIONALE FOR HVTN 702 IS BASED ON RV144

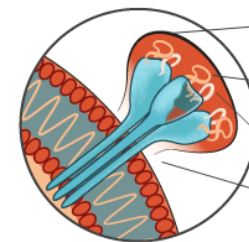


- Vaccine efficacy wanes



- magnitude, quality and durability of immune responses wanes

HIV ENVELOPE SPIKE



V1V2 loop  
V3 loop

**Correlates** associated with ↓HIV acquisition:

- Abs (**IgG, IgG3**) against envelope (vaccine-matched **gp120, V1V2**)
- **Functionality**, polyfunctionality scores of env-specific **CD4+ T-cell responses**





# HVTN 702

Grp	N= 5400	Month 0, Month 1	Month 3, Month 6, Month 12, Month 18
V	2700	ALVAC-HIV (vCP2438)	ALVAC-HIV (vCP2438) + Bivalent Subtype C gp120 & MF59®
P	2700	Placebo	Placebo + Placebo

14 trial sites in South Africa

~600 site research staff

5407 enrolled by June 2019

>200 000 PBMC vials

**Repository**

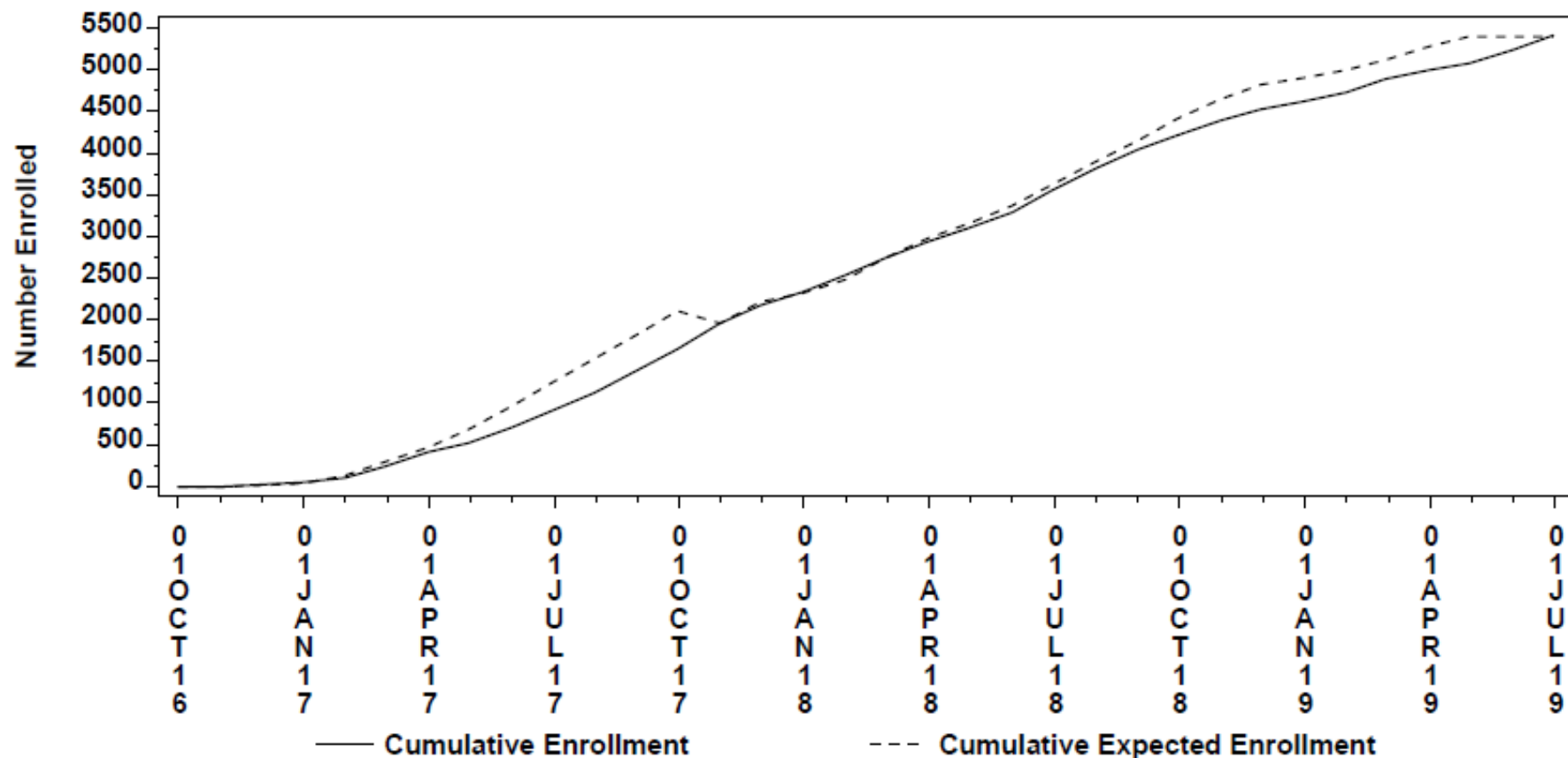
- DBS = 815 spots
- Plasma = 236,843 vials
- Serum = 474,859 vials
- Stool = 8,107 swabs



# HVTN 702: Cumulative Enrollment through 09SEP2019

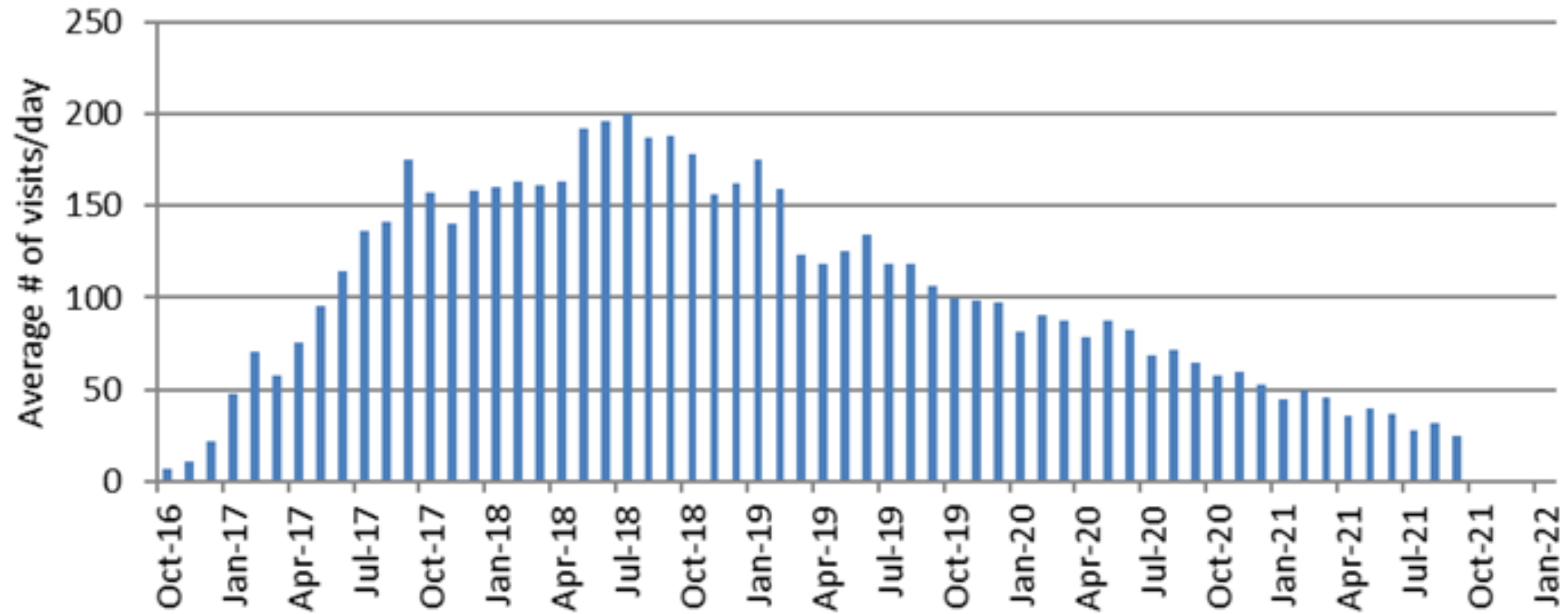
Targeted Full Enrollment: 5400

Total Enrolled: 5407    Total Expected: 5400    Shortfall: -7



# HVTN 702 Model

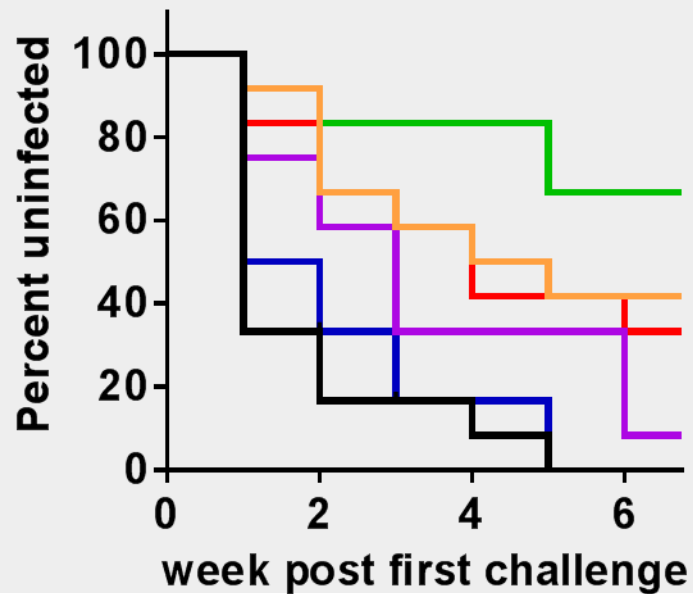
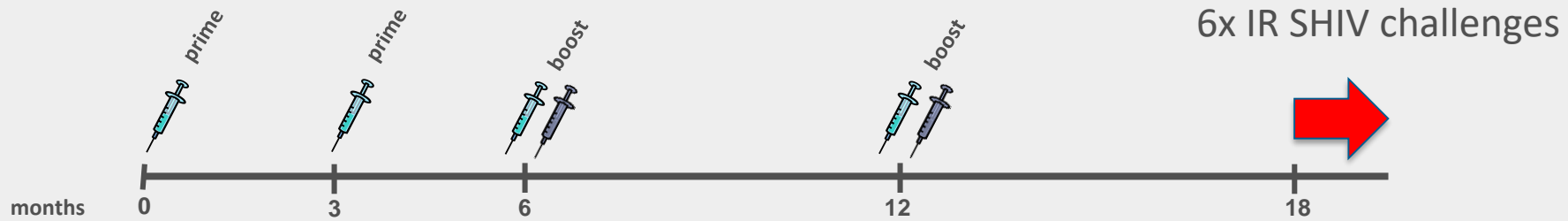
## # of Visits per day, by month



# RATIONALE FOR HVTN 705:

## The Ad26/Ad26+Env HIV vaccine regimen provides substantial protection against SHIV<sub>SF162P3</sub> challenges in non-human primates

[study designed to mimic APPROACH trial (HIV-V-A004)]



- Ad prime / Ad boost
- Ad prime / Env boost
- Ad prime / Ad+Env boost
- Ad prime / MVA boost
- Ad prime / MVA+Env boost
- Sham

N = 12  
per group

	Per-Exposure Risk Reduction	Full Protection after 6 challenges
Ad26/Ad26+Env	94%	67%
Ad26/MVA+Env	87%	42%
Ad26/Env	84%	33%



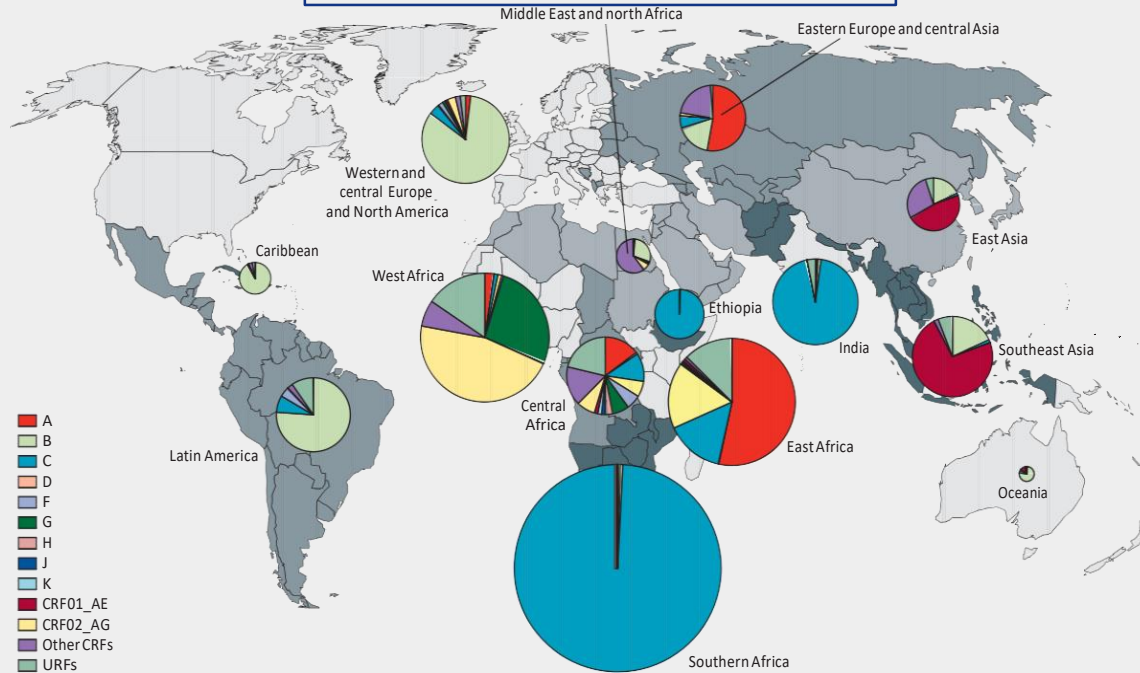
# RATIONALE FOR HVTN 705/HPX2008: Vaccine Aiming at Protection Against all Clades of HIV-1



 **Mosaic design**


For coverage of globally circulating HIV strains

**Heterologous vaccine regimen** using **Ad26** vectors expressing **mosaic** Gag, Pol and Env antigens, and soluble trimeric **gp140** envelope proteins:




**Ad26.Mos4.HIV**

For the induction of potent cellular and humoral immunity



**Trimeric envelope proteins**





For the enhancement of HIV-specific humoral immunity

# Mixture of 4 mosaic Ad26 constructs + gp140 Clade C boost



Vaccination at month 0, 3

**Ad26.Mos4.HIV**  
Ad26 vectors with Mosaic gag-pol or env inserts

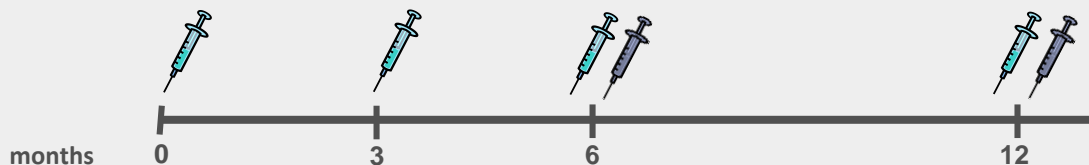

-  Ad26.Mos1.Gag-Pol
-  Ad26.Mos2.Gag-Pol
-  Ad26.Mos1.Env
-  Ad26.Mos2S.Env

Vaccinations at month 6, 12

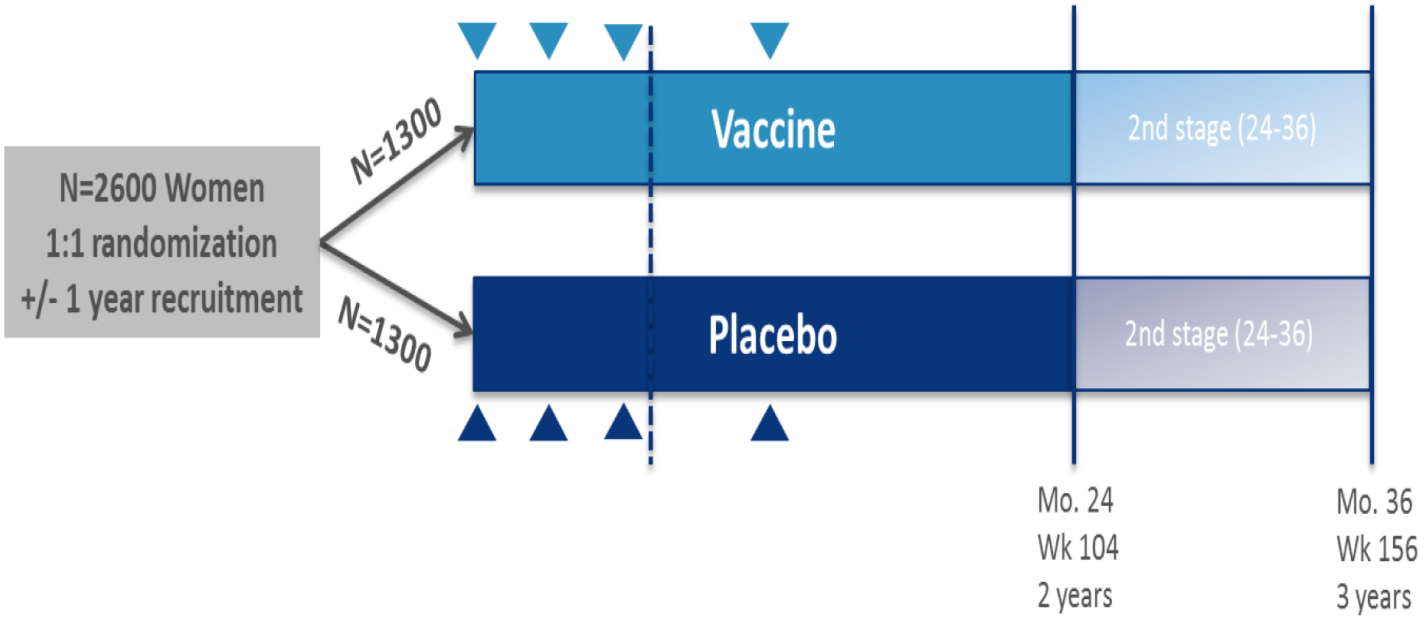
**Ad26.Mos4.HIV**  
gag-pol-env

+

**gp140 Clade C**  
Soluble trimer gp140 env proteins



# HVTN 705 STUDY DESIGN AND STAGES



23 sites in 5 countries

~600 site staff

2,637 enrolled

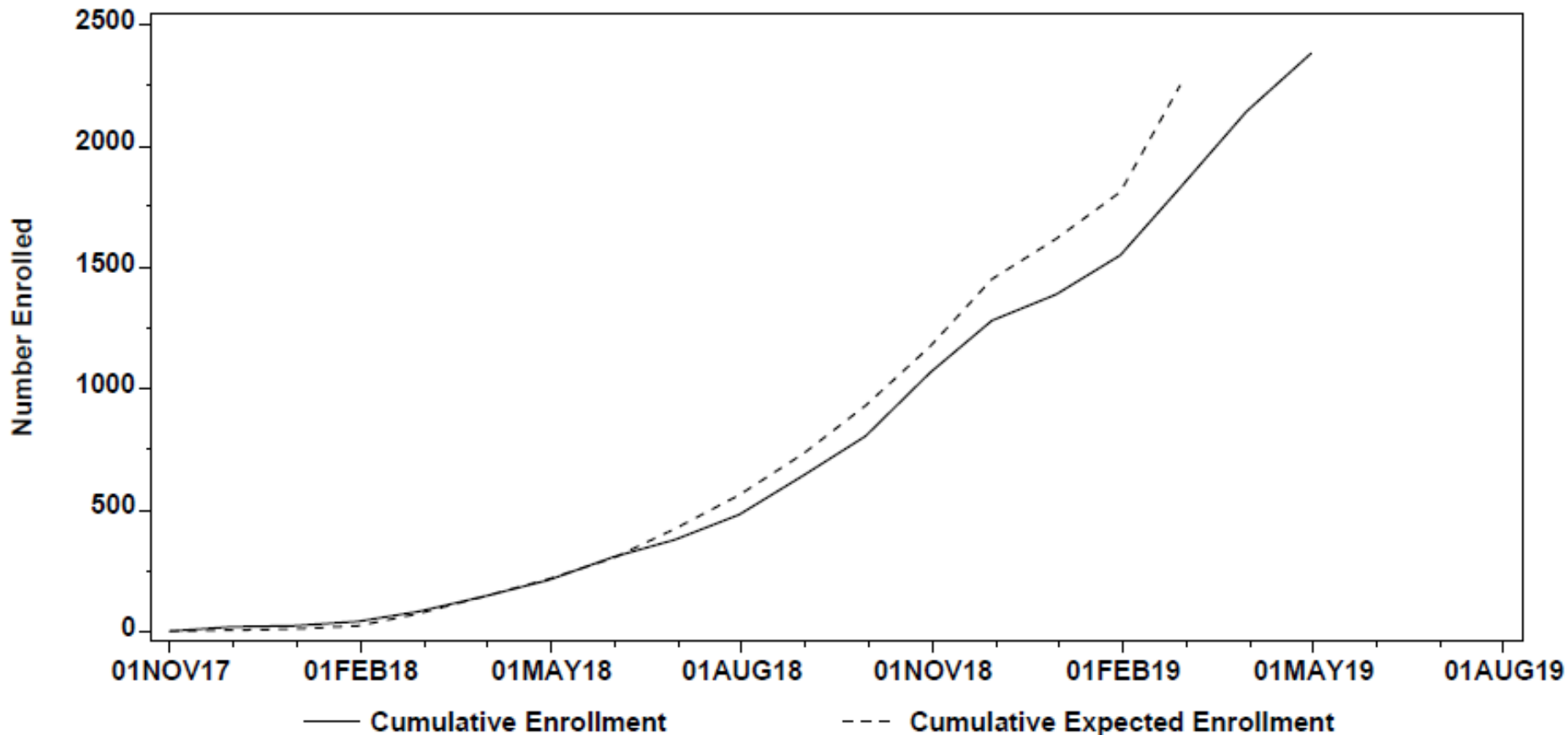
~111,122 PBMC vials

- ### Repository
- DBS = 765 spots
  - Tempus = 5,880 tubes
  - Plasma = 54,727 vials
  - Serum = 209,538 vials
  - Cervico-vaginal secretions fluid = 5,670
  - Cervico-vaginal secretions mucus = 23,278
  - Vaginal swabs = 5,339

# HVTN 705: Cumulative Enrollment through 06JUN2019

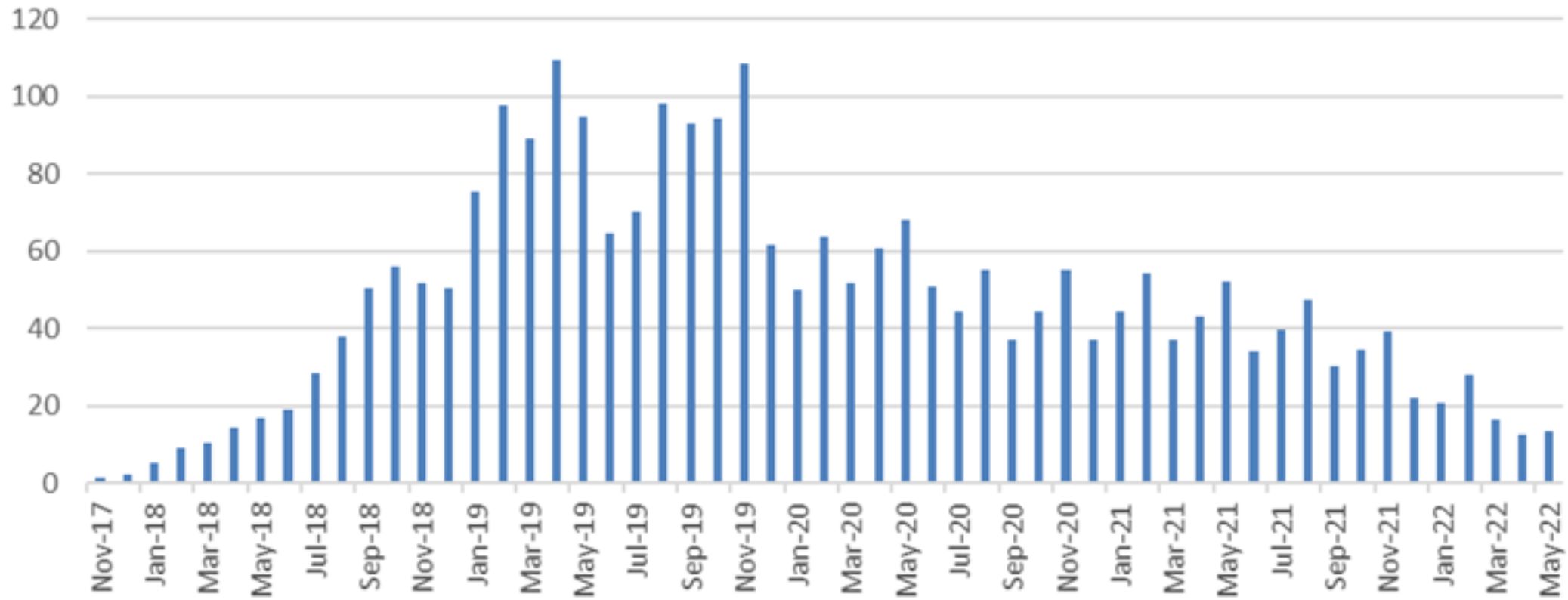
Targeted Full Enrollment: 2600

Total Enrolled: 2637    Total Expected: 2600    Shortfall: -37





### HVTN 705 Model: Avg no of visits/day



# BASELINE RISK CHARACTERISTICS: WOMEN

Trial	HVTN 702	HVTN 705
Females enrolled	3786	2637
Number of sexual partners in the last 30 days	2	2
Median Age & Distribution	24 (21-27)	23 (20-25)
Age <25	58.8%	68.8%
Condom Use (always)	5.5%	11.7%
Unknown status of partner/s	44.1%	46.9%
Oldest partner $\geq$ 5 years older	54.8%	66.4%

# BASELINE RISK CHARACTERISTICS: WOMEN

Trial	HVTN 702	HVTN 705
Transactional Sex	20.9%	54.5%
Not living with main partner	80.7%	84.6%
Main partner has other partners	26.1%	29.6%
Chlamydia	23%	20.8%
Any STI	29.8%	31.7%
Behavioural Risk Score 4-5	34.1%	27%
6-7	47.5%	43.1%
8-11	14.5%	26.2%

# BASELINE RISK CHARACTERISTICS: CONTRACEPTION

Trial	HVTN 702	HVTN 705
Male Condoms	21.2%	7.3%
IUDs	2.5%	2.0%
Implants	11.3%	22.6%
Injectables	80.6%	68.8%
Oral Contraception	5.1%	6.3%

# MALE ENROLMENT IN HVTN 702 (N=1621)

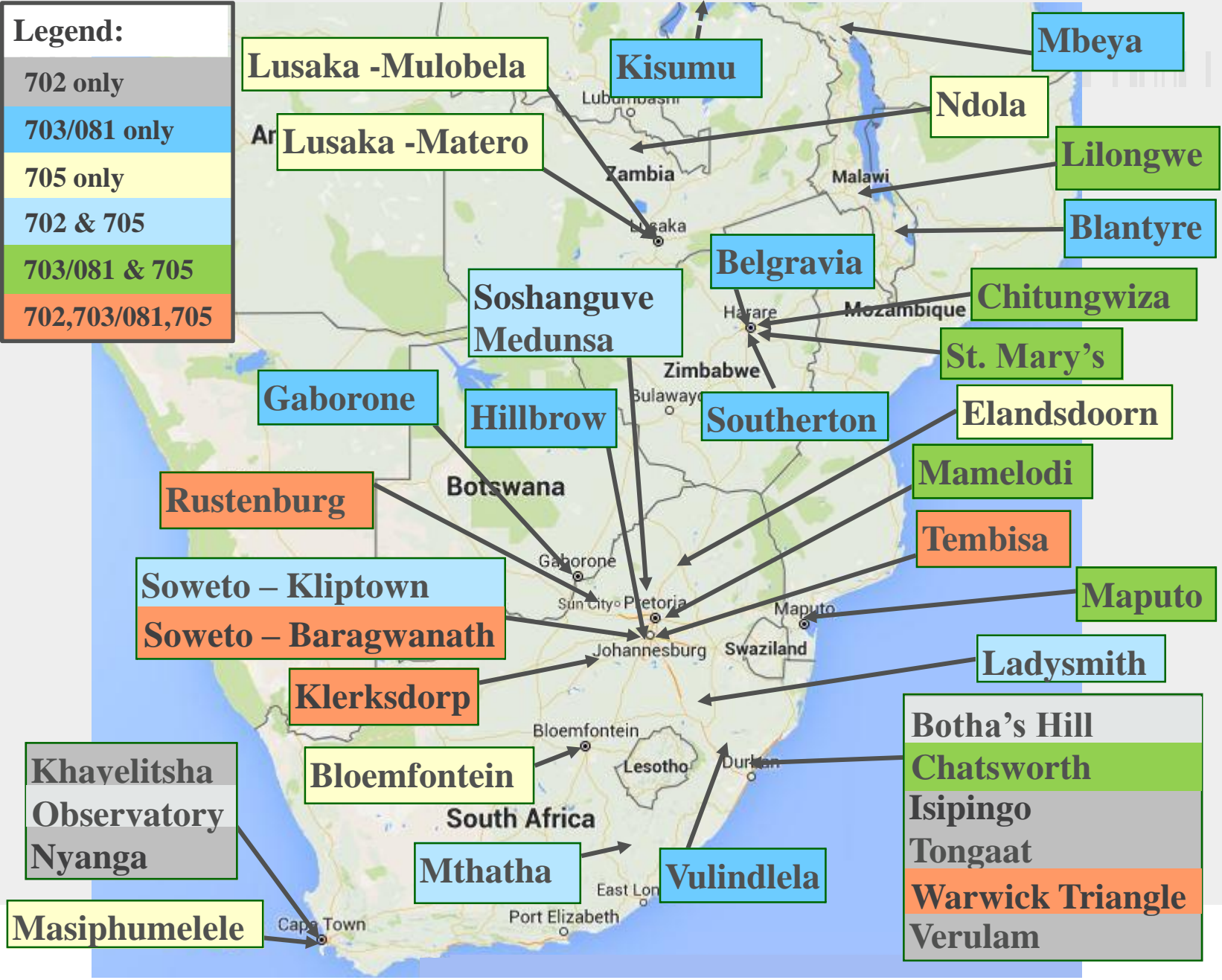
	Heterosexual (87.6%)	Non-Heterosexual (12.3%)
Age		
18-20	10.8%	30.3%
21-25	32.1%	45.3%
26-30	32.5%	18.4%
31-35	24.6%	6.0%
Circumcised	53.8%	49.3%
Always uses condoms	8.3%	10.9%
Knowledge of partner's status	48.6%	68.7%
Living with main partner	18.2%	10.0%

# MEN ENROLMENT IN HVTN 702 (N=1621)

	Heterosexual (87.6%)	Non-Heterosexual (12.3%)
Exchanged money/gifts for sex	12.3%	41.3%
Main partner has other partners	12.7%	21.4%
STI: Syphilis	1.5%	5.3%
Gonorrhoea	2.3%	8.5%
Chlamydia	14.1%	26.6%
Any STI	16.2%	30.9%
Behavioural Risk Score		
1	23.6%	12.4%
2	50.8%	33.3%
3	21.0%	38.2%
4	2.1%	14.0%
Anal Sex		89.6%

**Legend:**

- 702 only
- 703/081 only
- 705 only
- 702 & 705
- 703/081 & 705
- 702,703/081,705



**WE ARE WORKING HARD TO ACHIEVE THESE NUMBERS**

**These are the trailblazers in this heroic endeavor**

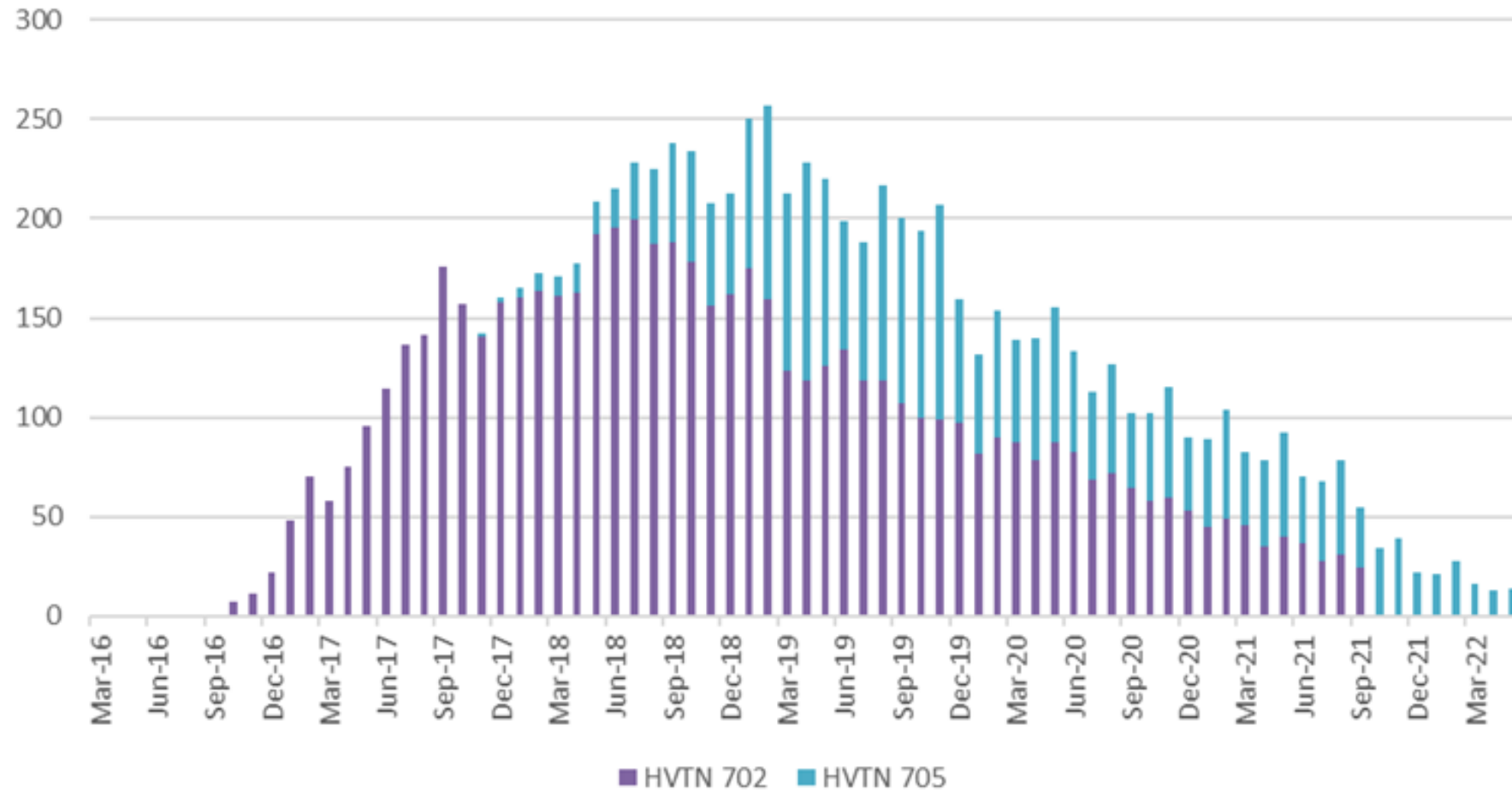


# PROGRAM TEAM ON THE GROUND SUPPORTING SITE OPERATIONS

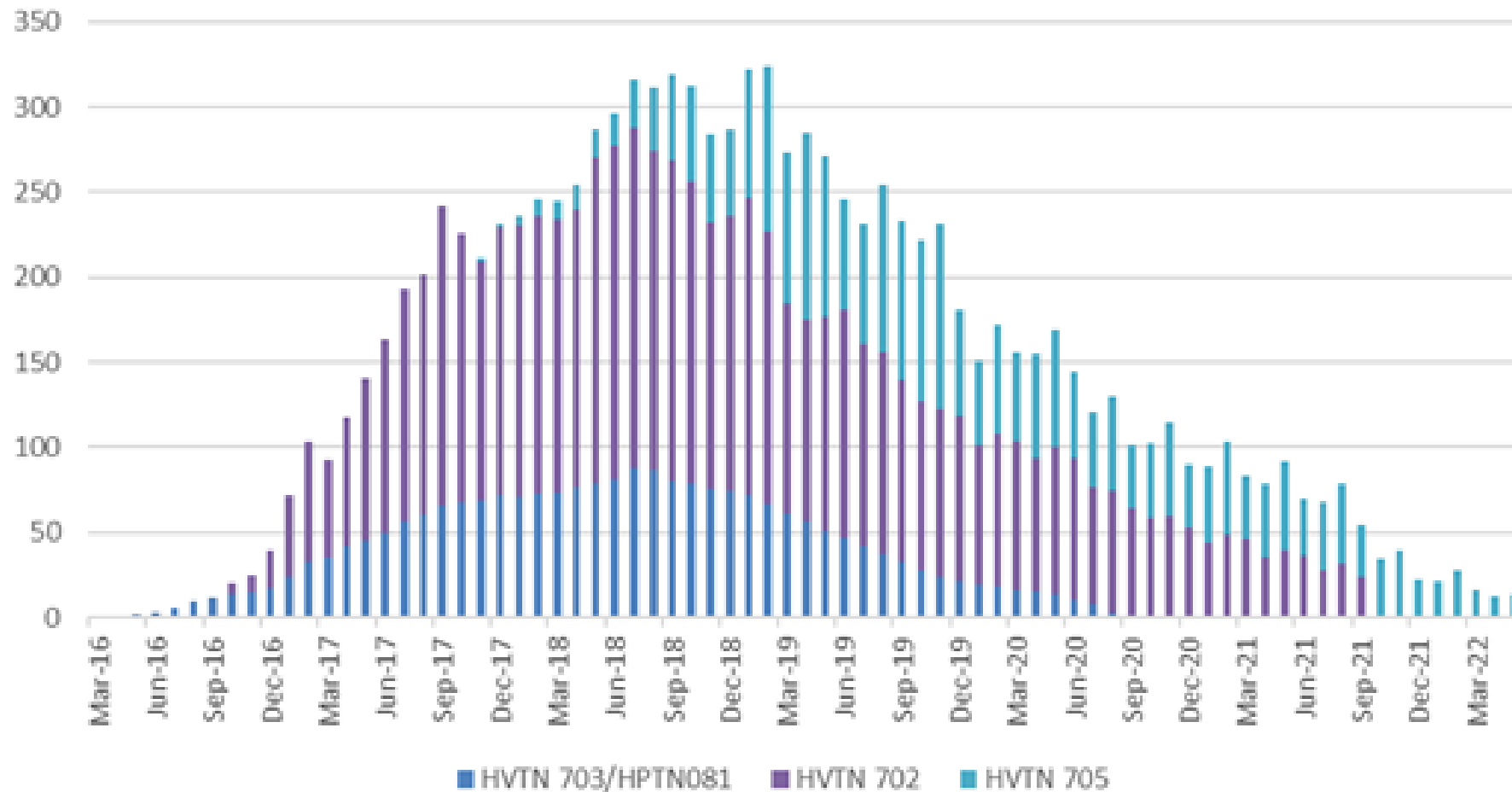
Clinical Trial Managers	Site Liaison Team	Community Engagement Unit	Safety Monitoring	Laboratory Support	Protocol Leadership
<ul style="list-style-type: none"><li>• Site development &amp; support</li><li>• Protocol implementation &amp; management</li><li>• Training</li><li>• Stakeholder Communication</li></ul>	<ul style="list-style-type: none"><li>• Data Quality</li><li>• Audit readiness</li><li>• Participants rights and well-being</li><li>• Regulatory assurance</li></ul>	<ul style="list-style-type: none"><li>• Site CER education</li><li>• Community education</li><li>• CAB support</li><li>• Giveaway materials/study branding</li></ul>	<ul style="list-style-type: none"><li>• Site clinical support</li><li>• Participant safety</li><li>• Scientific liaison resource</li><li>• Protocol development and implementation</li></ul>	<ul style="list-style-type: none"><li>• QA &amp; compliance</li><li>• Site lab study preparation</li><li>• LDMS support</li><li>• Certification programs &amp; training inc. PBMC proficiency</li></ul>	<ul style="list-style-type: none"><li>• Integrated operations oversight &amp; support</li><li>• Liaison with site operations /study /scientific operations teams</li><li>• Execution of strategic projects/ initiatives/ priorities</li><li>• Stakeholder collaboration</li></ul>



## Average Number of Participant Visits per day: HVTN 702 and HVTN 705



## Average Number of Participant Visits per day: HVTN Efficacy Trials in SSA



# HVTN 702: 563,871 CRF PAGES ENTERED TO DATE

Site	// Data Management Quality						
	Total # Pages Entered Thru 8/31/2019	Total # Queries Thru 8/31/2019	Queries per 100 Pages Thru 8/31/2019	% Queries Resolved on Time Thru 8/31/2019	# Pages Included in Time Metric Thru 8/31/2019	% Pages on Time Thru 8/31/2019	% AE on Time Thru 8/31/2019
Cape Town - Emavundleni	50,810	2,112	4.2	77%	28,666	94%	84%
Cape Town - Khayelitsha	41,065	1,071	2.6	81%	24,015	99%	86%
Durban - eThekweni	38,824	1,515	3.9	83%	23,448	99%	93%
Durban - Isipingo	53,270	1,633	3.1	70%	29,957	95%	94%
Durban - Verulam	50,041	1,641	3.3	62%	29,977	93%	90%
Klerksdorp	40,120	1,895	4.7	74%	23,230	96%	80%
Ladysmith	39,459	549	1.4	72%	24,079	89%	85%
Medunsa	33,932	1,209	3.6	70%	20,280	95%	77%
Mthatha	4,155	398	9.6	75%	2,183	87%	68%
Rustenburg	36,514	1,817	5.0	66%	21,481	94%	78%
Soshanguve	54,838	2,325	4.2	84%	32,983	93%	75%
Soweto - Bara	53,357	1,544	2.9	91%	29,303	98%	85%
Soweto - Kliptown	35,016	676	1.9	86%	19,640	97%	91%
Tembisa - Clinic 3	32,470	1,593	4.9	75%	18,526	94%	71%
	<b>563,871</b>	<b>19,978</b>	<b>3.5</b>	<b>76%</b>	<b>327,768</b>	<b>95%</b>	<b>84%</b>



# HVTN 705: 172,647 TOTAL PAGES ENTERED

Site	// Data Management Quality						
	Total # Pages Entered Thru 7/31/2019	Total # Queries Thru 7/31/2019	Queries per 100 Pages Thru 7/31/2019	% Queries Resolved on Time Thru 7/31/2019	# Pages Included in Time Metric Thru 7/31/2019	% Pages on Time Thru 7/31/2019	% AE on Time Thru 7/31/2019
Bloemfontein	11,991	346	2.9	97%	5,900	94%	61%
Durban - Chatsworth	13,536	228	1.7	85%	6,956	95%	99%
Durban - eThekweni	2,599	17	0.7	100%	1,281	100%	95%
Durban - Tongaat	6,478	76	1.2	77%	3,067	93%	97%
Elandsdoorn	10,606	676	6.4	77%	5,543	94%	72%
Harare - Seke South	14,192	193	1.4	98%	7,442	99%	95%
Harare - St. Mary's	7,553	213	2.8	92%	3,871	96%	82%
Klerksdorp	2,766	56	2.0	98%	1,179	94%	100%
Ladysmith	11,480	138	1.2	98%	6,191	96%	85%
Lilongwe	9,781	329	3.4	92%	5,161	91%	80%
Lusaka - Matero	7,409	199	2.7	61%	3,049	96%	66%
Lusaka - ZEHRP	6,614	274	4.1	92%	3,373	96%	78%
Mamelodi	12,320	647	5.3	89%	6,317	97%	86%
Maputo	1,974	71	3.6	93%	819	87%	40%
Masiphumelele	13,522	289	2.1	96%	7,086	97%	89%
Medunsa	1,456	20	1.4	100%	595	100%	100%
Mthatha	242	12	5.0	67%	86	94%	0%
Ndola	5,883	128	2.2	100%	3,113	97%	73%
Rustenburg	2,189	44	2.0	82%	955	93%	100%
Soshanguve	6,633	163	2.5	92%	2,969	96%	98%
Soweto - Bara	18,086	342	1.9	96%	9,050	99%	84%
Soweto - Kliptown	2,152	4	0.2	100%	890	96%	83%
Tembisa - Clinic 4	3,185	42	1.3	98%	1,261	99%	97%
<b>TOTAL</b>	<b>172,647</b>	<b>4,507</b>	<b>2.6</b>	<b>89%</b>	<b>86,154</b>	<b>96%</b>	<b>83%</b>



# HVTN 702: ALMOST 46,000 STUDY VISITS COMPLETED

Site	Total Visits		
	<i>Compl</i>	<i>Exp</i>	<i>%</i>
Cape Town - Emavundleni	3,833	4,289	89%
Cape Town - Khayelitsha	3,340	3,659	91%
Durban - eThekweni	3,302	3,398	97%
Durban - Isipingo	4,382	4,657	94%
Durban - Verulam	4,364	4,732	92%
Klerksdorp	3,333	3,606	92%
Ladysmith	3,422	3,803	90%
Medunsa	2,819	2,983	95%
Mthatha	251	278	90%
Rustenburg	3,011	3,286	92%
Soshanguve	4,408	4,881	90%
Soweto - Bara	3,971	4,387	91%
Soweto - Kliptown	2,728	2,943	93%
Tembisa - Clinic 3	2,621	3,076	85%
	<b>45,785</b>	<b>49,978</b>	<b>92%</b>

- Vaccine administration visits:  
~128,400 participant visit hours
- Other visits:  
~60,315 participant visit hours

# HVTN 705: OVER 10,000 STUDY VISITS COMPLETED

Site	Total Visits		
	<i>Compl</i>	<i>Exp</i>	<i>%</i>
Bloemfontein	793	884	90%
Durban - Chatsworth	885	949	93%
Durban - eThekweni	143	144	99%
Durban - Tongaat	372	436	85%
Elandsdoorn	710	766	93%
Harare - Seke South	973	1,043	93%
Harare - St. Mary's	454	474	96%
Klerksdorp	123	123	100%
Ladysmith	840	870	97%
Lilongwe	643	674	95%
Lusaka - Matero	331	350	95%
Lusaka - ZEHRP	386	407	95%
Mamelodi	924	996	93%
Maputo	86	88	98%
Masiphumelele	905	935	97%
Medunsa	58	58	100%
Mthatha	7	7	100%
Ndola	363	393	92%
Rustenburg	89	96	93%
Soshanguve	272	281	97%
Soweto - Bara	997	1,083	92%
Soweto - Kliptown	87	87	100%
Tembisa - Clinic 4	137	142	96%
	<b>10,578</b>	<b>11,286</b>	<b>94%</b>

- Vaccine administration visits:  
~32,740 participant visit hours
- Other visits:  
~12,090 participant visit hours

# DRIED BLOOD SPOTS COLLECTED FOR PREP

HVTN 702	2 134
HVTN 703	2 112
HVTN 705	1 106
<b>Total</b>	<b>5 352</b>

# PREP UPTAKE

	HVTN 702	HVTN 705
N	5,407	2,637
PrEP	119	91
% users ever	2.2%	3.5%



# PBMC COLLECTION

HVTN 702	20 058
HVTN 705	9 693
HVTN 703	6 012
<b>Total</b>	<b>35 763</b>

# HIV DIAGNOSTIC ALGORITHMS RUN BY PROTOCOL:

- **HVTN 702: 33,099**
- **HVTN 703: 38,146**
- **HVTN 705: 10,973**

Run at NICD in Adrian Puren's lab by 5 people!

# VISIT COMPLETION

## 702 Visit Completion total

Protocol	Vaccination 2	Vaccination 3	Vaccination 4	2 week post-vacc 4	Vaccination 5	2 week post-vacc 5	Vaccination 6	2 week post-vacc 6	Follow-up visit
HVTN702	95%	94%	91%	88%	87%	84%	86%	82%	87%

## 705 Visit Completion total

Protocol	Vaccination 2	Vaccination 3	1 day post-vacc 3	4 weeks post-vacc 3	Vaccination 4	4 weeks post-vacc 4	Follow-up visit
HVTN705/HPX2008	93%	91%	98%	88%	88%	87%	90%

### Overall Visit Retention

**HVTN 702: 91%**

**HVTN 705: 93%**

# TIPS FOR THE TALE OF TWO TRIALS: A CASE STUDY FROM MECRU



Successfully Retaining high risk participants in the HVTN 702 and HVTN 705 trials: Considerations, Tips, and Recommendations.

M Lekalakala



## The retention officer in 702 and 705

- HVTN 702 total enrolment 333: retention rate 93% past 2 months;
- HVTN 705 total enrolment 39: retention rate 96% past 2 months;
- Role of retention officer is a dedicated post in the structure of MeCRU.
- Supported by recruiters of the site;
- Running only two studies at a time;

## Retention officer: passionate about retention

1. Taking things personal about failing to get participants to come to site;
2. Take disappointment personal and serious;
3. Get personal fulfilment when getting it right; run by the maxim “He left the 99 to go and find the 1 sheep missing”
4. Become so passionate that you forget that you work with a team.  
This keeps you very motivated to the exclusion of everyone else.
5. Sharing personal qualities with the team influences everyone: love the participants as family; treat them as your own; appreciating the difficulty of recruitment

## Difficult things in retention

- Inaccurate locators: be patient until you get the truth about where to find the participants;
- Change of contact details: they use different sim cards at a time;
- For participants who become incarcerated, are difficult to follow through; and keep contact to keep them encouraged;
- New Employment: not able to take time off work;
- Staff attitude that are discouraging;
- Not flagging possible defaulters in time;
- Refreshments not appealing to participants-lead to complaints.

## Some solutions to the difficulties

**Planning – proper planning that accommodates the participant’s schedule.**

**For the employed, Saturday and Sunday clinics are useful;**

**Early mornings and late afternoon schedules;**

**Relocation - we pay for transport to come to site**

**Prisoners: Keep in touch with the family of the convicts so that when they are released we can find them;**

**Build relationships with the participants;**



## Tips and recommendations

- Found the tracking tool of pharmacy more reliable for participants scheduled for vaccination;
- Recruitment allows for self selection of quality participants. We would forego participants that require to be pushed to participate;
- Focus on problematic participants. Encourage the reliable and consistent ones.
- Do not break your promises;
- Go an extra mile to meet the needs of the participants; be restless when there is a defaulter;
- Continue education between visits with long breaks.

## Tips and recommendations

- ❑ It is important to remind participants BUT also do your part;
- ❑ Two stories I can tell you:
  - Retaining a participant that went for traditional healing training;
  - Going the extra mile in times of distress.
- ❑ It is important to understand that you are dealing with a high risk group of ages 18 to 35.



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