

NO DATA NO MORE:

A RESEARCH SCORECARD FOR TRANSGENDER INCLUSION



Brian Minalga, MSW

HANC Deputy Director

John Meade, MPH

AVAC Senior Program Manager





AGENDA

1. The State of TGD Inclusion

Intro

Quiz

What We Found: 1991-present

2. The Manifesto & Scorecard

Scorecard Tool Debut!

Activity

3. Discussion

TGD People in HIV Research

- Without meaningful trans inclusion, there is no end to the HIV epidemic.
- Research with cis people cannot be generalized to trans people.
- TGD people are not all the same.





QUIZ

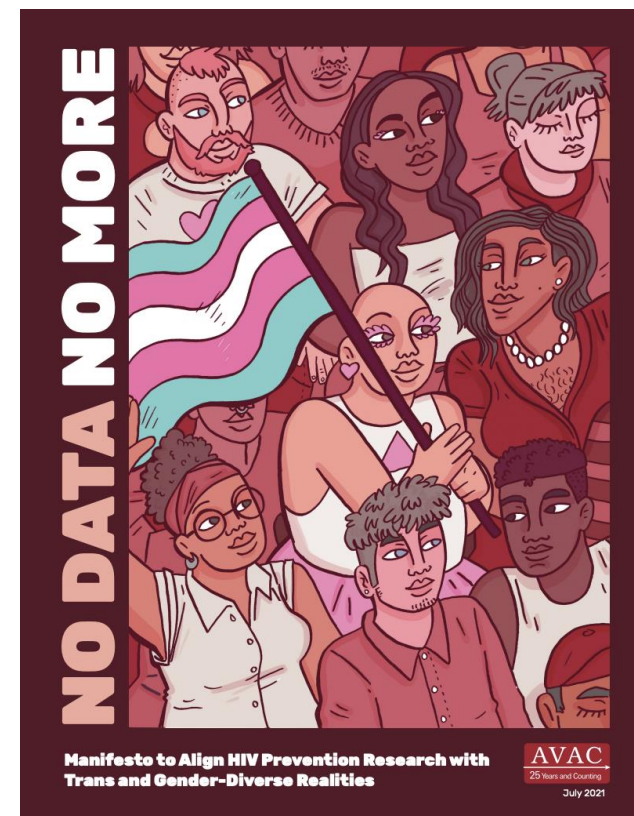


The State of Trans Inclusion in HIV Research



The Manifesto

- Launched by AVAC in July 2021
 - Shout Out: Cindra Feuer
- TGD consultants from around the globe
- Lit review, surveys, interviews, workshops
- More than 2 dozen visions in 3 areas:
 - TGD Lived Experiences
 - Gender-Affirming Hormone Therapy (GAHT)
 - Integration into HIV Research Agenda
- Roadshow: >20 dialogues with community, pharma, government, and more



Trans Inclusion Scorecard

- Synthesis of the Manifesto into 13 scoreable indicators
- Scorecard release: Today!
- Advocacy for a more inclusive future



Scorecard in Action: Landscape Analysis

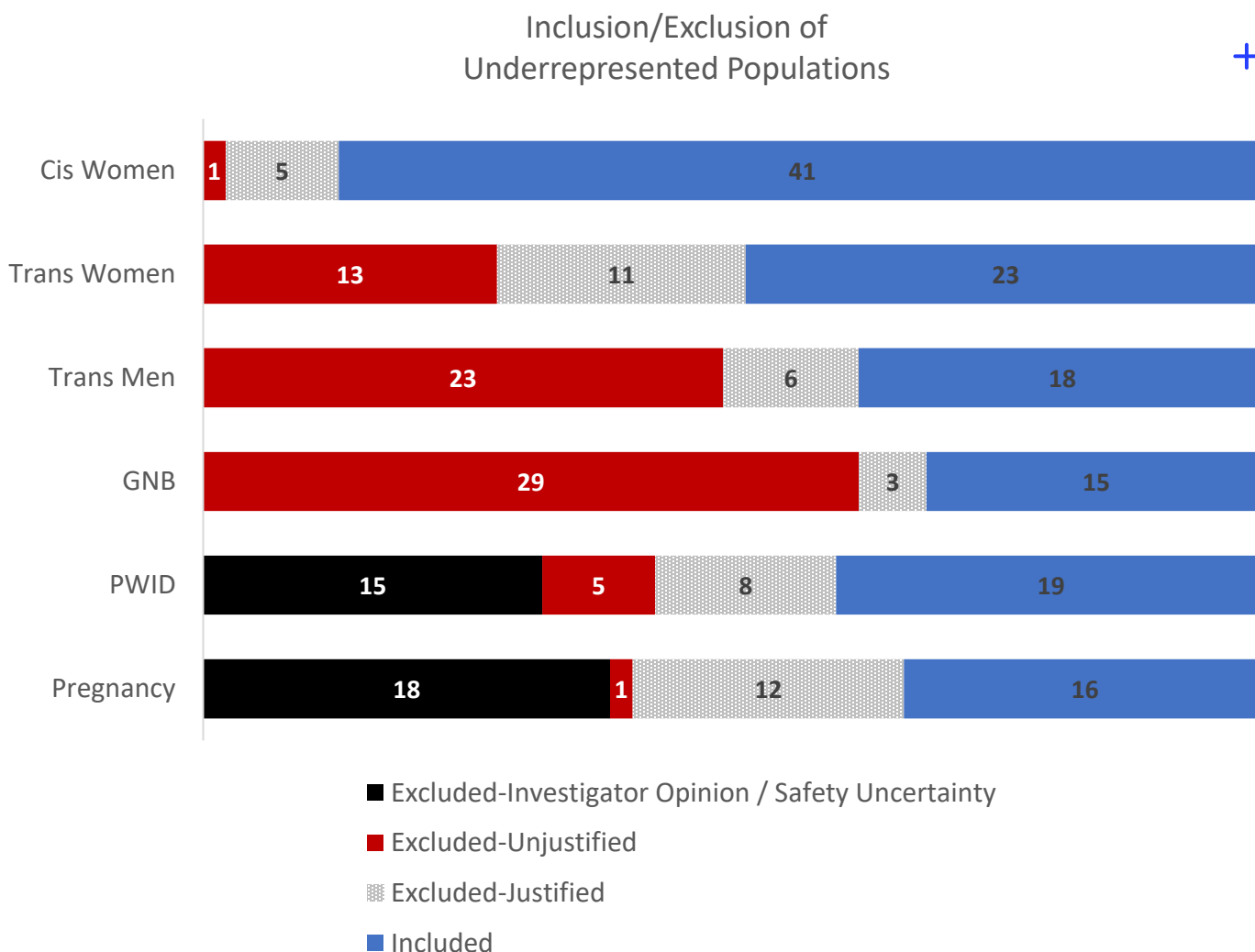
- Assessed over 30 years of milestone HIV clinical trials
 - Study protocols, publications, and records on clinicaltrials.gov
 - Shout Out: Richard Jefferys (TAG)
- Based on the Representative Studies Rubric (RSR) developed at HANC





The RSR

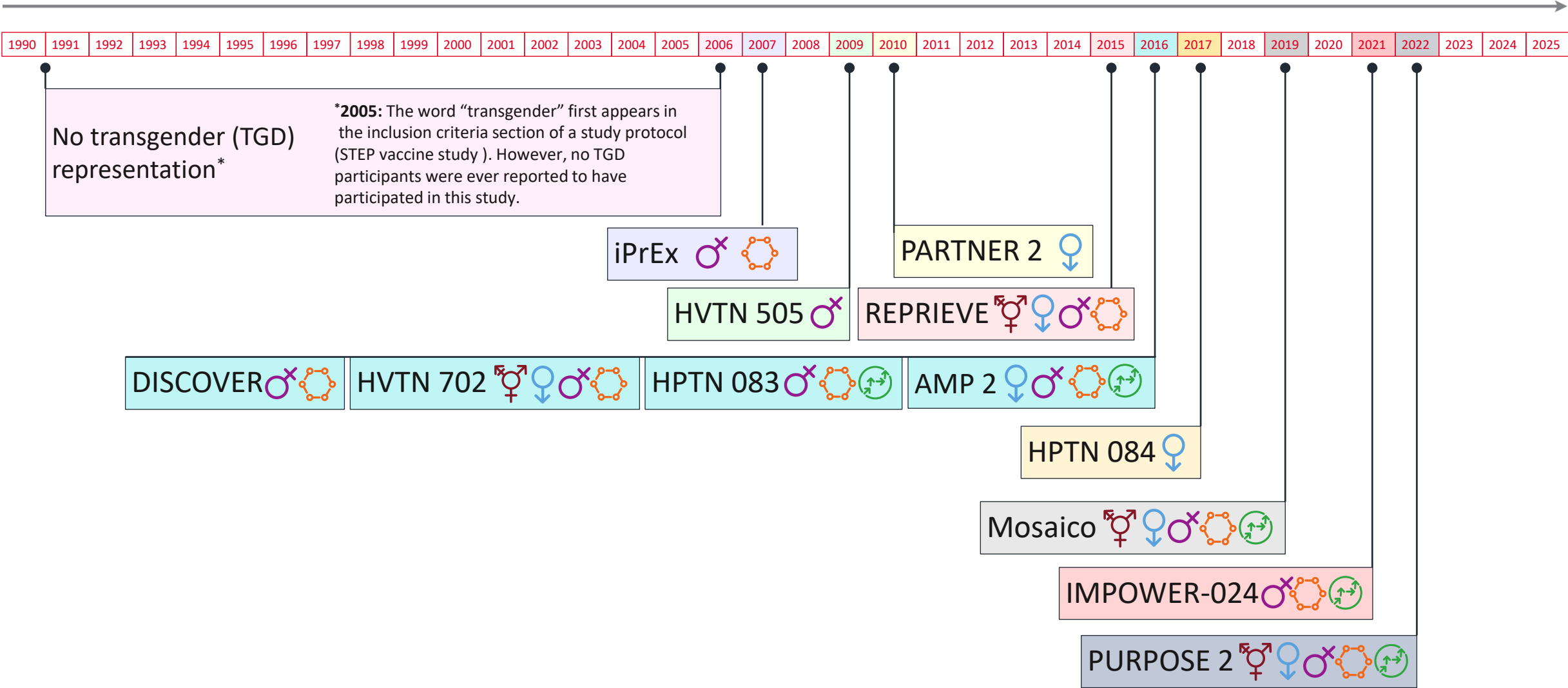
- Age
- Assigned Sex
- Drug Use
- Ethnicity
- Gender
- Pregnancy
- Race
- Language



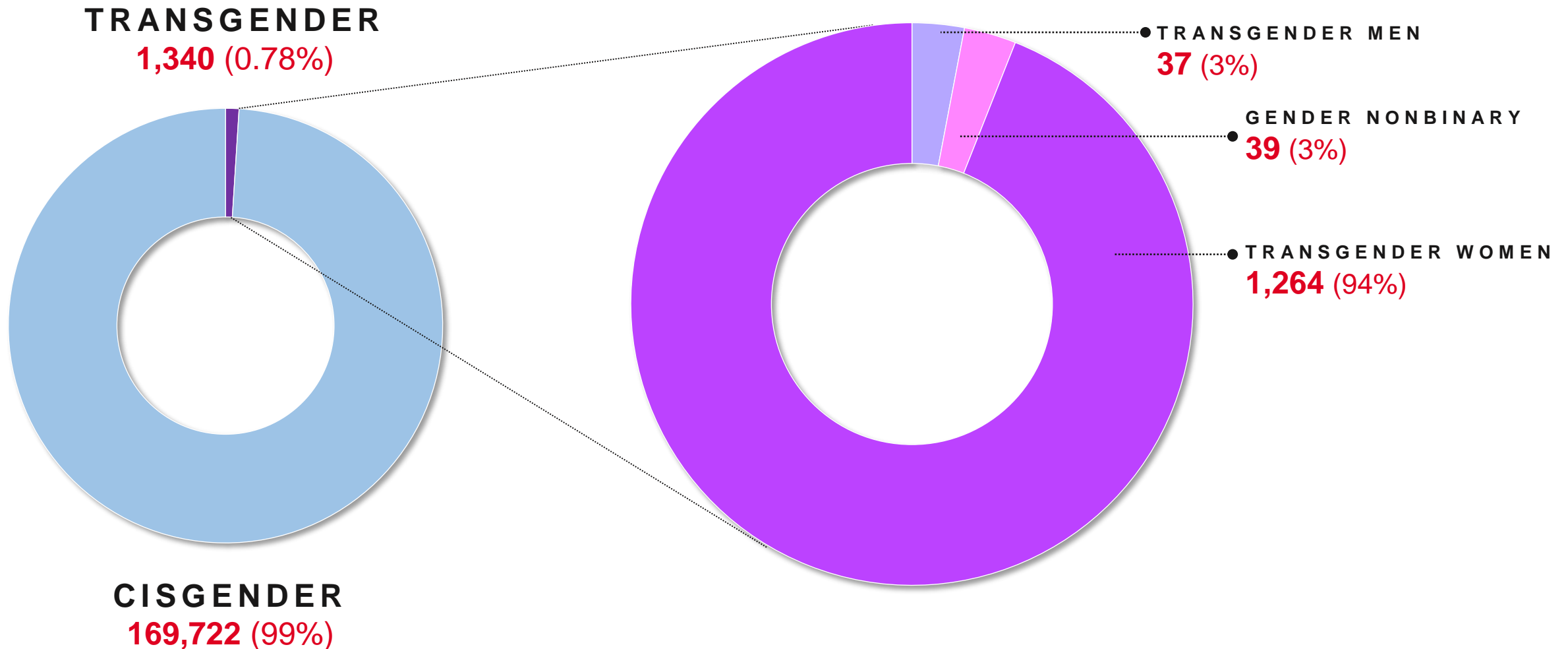
Scorecard Analysis: 41 Studies, 1991-present

Treatment (11)	Vaccine & Antibody (11)	PrEP & Microbicides (19)	
ACTG 175 (1991-1992)	Vax Gen (1998-1999)	iPrEx (2007-2009)	The Ring Study (2012-2016)
Ritonavir Study (1995)	Thai Trial (2003-2005)	TDF2 (2007-2009)	DISCOVER (2016-2017)
ACTG 320 (1996-1997)	STEP Study (2005-2007)	Bangkok Tenofovir Study (2005-2010)	HPTN 083 (2016-2020)
SMART (2002-2006)	Phambili Study (2007)	CAPRISA 004 (2007-2010)	HPTN 084 (2017-2020)
HPTN 052 (2005-2010)	HVTN 505 (2009-2013)	Partners PrEP (2008-2010)	Impower-022 (2021-2022)
START (2009-2013)	HVTN 702 (2016-2019)	FEM-PrEP (2009-2011)	Impower-024 (2021-2022)
PARTNER 1 (2010-2014)	Imbokodo (2017-2019)	VOICE (2009-2011)	PURPOSE 1 (2021-ongoing)
PARTNER 2 (2010-2017)	Mosaico (2019-2023)	FACTS 001 (2011-2014)	PURPOSE 2 (2022-ongoing)
Opposites Attract (2012-2016)	PrEPVacc (2020-ongoing)	IPERGAY (2012-2014)	
PopART (2013-2017)	AMP 1 (2016-2018)	PROUD (2012-2014)	
REPRIEVE (2015-2019)	AMP 2 (2016-2018)	ASPIRE (2012-2015)	

Transgender Representation Over Time



Representation in Milestone HIV Clinical Trials



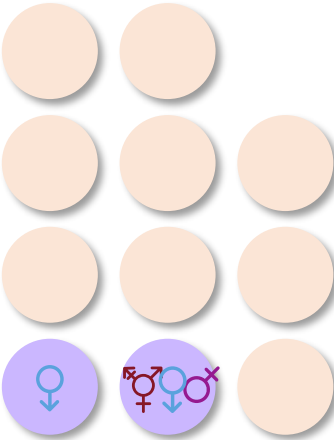
Preliminary Findings

Transgender Representation by Study Type

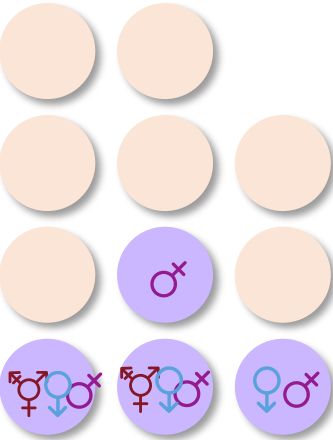
TREATMENT

VACCINE/AB

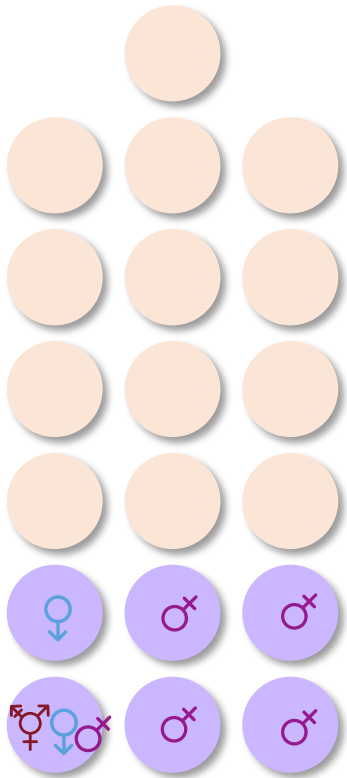
PREP/MICROBICIDE



11

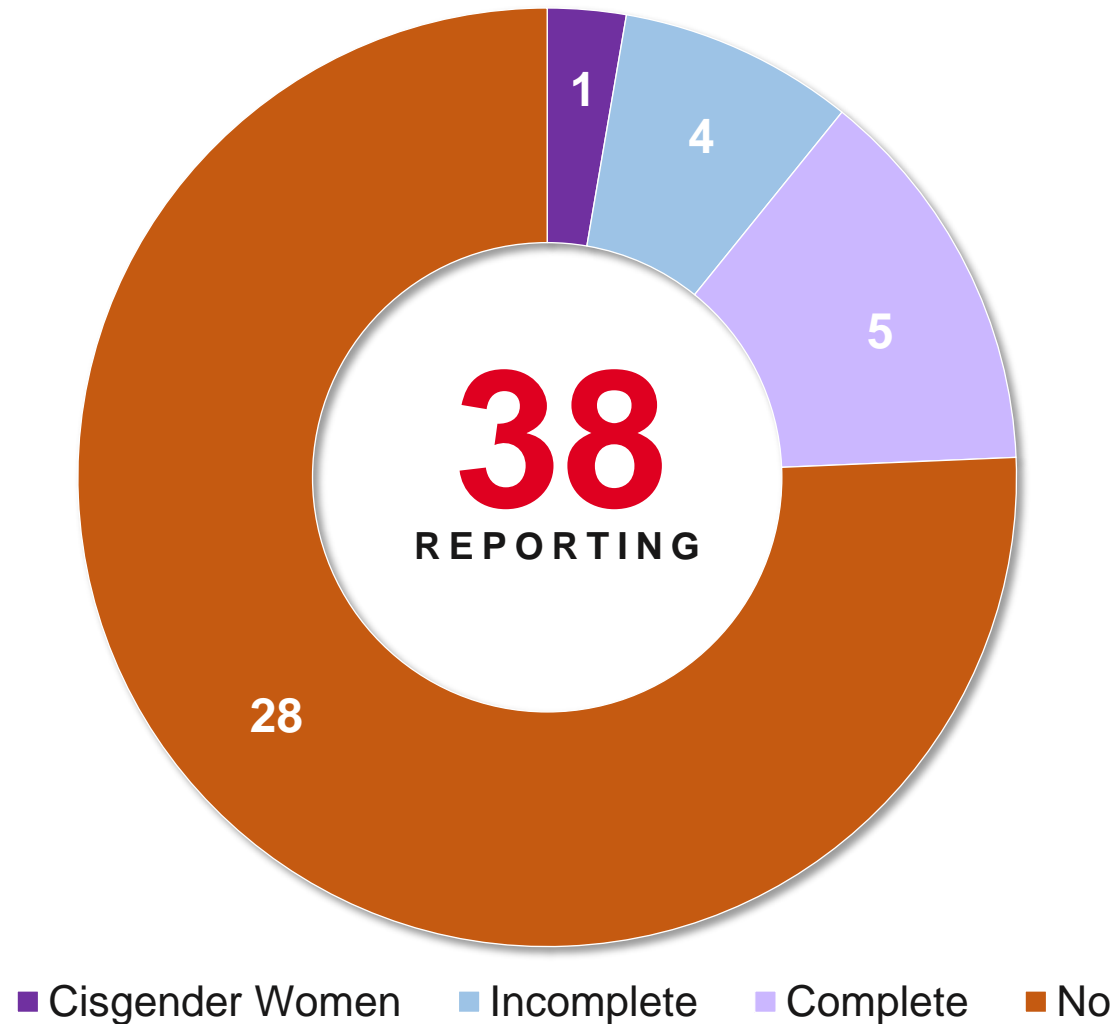


11



19

Studies Reporting Gender



Preliminary Findings

Conclusions

- Since 1991, **TGD people have made up less than 1% of participants** in 41 key HIV clinical trials (1,340 / 171,062).
 - Vast majority were trans women.
- 2007: First reported trans enrollment (iPrEx).
- Only 12 of the 41 trials analyzed included any TGD participants.
- Most HIV studies exclude TGD people but don't justify the exclusion.
- TGD-centered research questions and study design strategies are underutilized.

The Scorecard

Study Design	Study Implementation	Study Reporting	Language
Eligibility includes TGD people	Collection of TGD status	Number of GNB, TGM, & TGW reported	NIAID Language Guide applied
Justification for TGD exclusion	TGD-inclusive recruitment	TGD-specific results	
TGD enrollment goals	TGD staff	TGD limitations stated	
Hormones accounted for	Sites with proven experience		
	TGD community partnerships		

A: 11-13
B: 8-10
C: 5-7
D: 2-4
F: 0-1



SCORECARD

In Action



1. Selection Criteria include GNB, TM, and TW, discretely.

The PROUD Study

“Born to male gender.”

Mosaico

“**Cis-gender man** having sex with cis-gender men and/or transgender individuals OR

Transgender woman having sex with cis-gender men and/or transgender individuals OR

Transgender man having sex with cis-gender men and/or transgender women (transgender men having sex exclusively with transgender men is excluded OR

Gender non-conforming individual having receptive or insertive anal and/or vaginal condomless intercourse”

2. If TGD participants excluded, their exclusion is explicitly justified.

The AMP Study for Cis Women

“We note that a parallel study assessing the safety and preventive efficacy of VRC01 is being conducted among 2700 men and transgender persons who have sex with men or transgender persons in the Americas and Europe.”

VaxGen 004

“Insertive anal sex does not apply to women.”

3. TGD Enrollment Goals

HPTN 083

“The study overall will strive to enroll 10% TGW, and again, efforts to enrich enrollment with TGW will be a focus of education and outreach at all sites.”

570 TGW enrolled (12.5%)

HPTN 084

“Women, women, women.”

5 TGM enrolled (0.2%)

4. Hormones accounted for

Uhambo

Grading adverse events includes adjustments for “transgender participants ≥ 13 years of age who have been on feminizing/masculinizing hormone therapy for more than 6 consecutive months.”

REPRIEVE

TGD AMAB participants using GAHT had higher waist circumference compared to TGD AMAB participants not using GAHT.

5-9. Systems for Trans-Inclusive Study Implementation

PURPOSE 2

<https://www.purposestudies.com/purpose2/>

10-12. Study Reporting

Table 1. Characteristics of the Population Cohort at Baseline.*

Characteristic	Group A (N = 12,671)	Group B (N = 13,404)	Group C (N = 12,399)
	<i>number/total number (percent)</i>		
Sex			
Male	3595/12,637 (28)	3906/13,364 (29)	3701/12,340 (30)
Female	9042/12,637 (72)	9458/13,364 (71)	8639/12,340 (70)
Age			
18–24 yr	5065/12,636 (40)	5179/13,364 (39)	4981/12,336 (40)
25–34 yr	4928/12,636 (39)	5170/13,364 (39)	4688/12,336 (38)
35–44 yr	2643/12,636 (21)	3015/13,364 (23)	2667/12,336 (22)
Marital status			
Married or living as married	5363/12,560 (43)	5210/13,233 (39)	4693/12,199 (38)
Never married	6292/12,560 (50)	6923/13,233 (52)	6644/12,199 (54)
Divorced, separated, or widowed	905/12,560 (7)	1100/13,233 (8)	862/12,199 (7)

10-12. Study Reporting

Table 1. Baseline Characteristics of the Study Participants, According to Study Group and HIV-1 Serostatus.*

Characteristic	TDF (N = 1584 couples)		TDF-FTC (N = 1579 couples)		Placebo (N = 1584 couples)	
	Seronegative Partner	Seropositive Partner	Seronegative Partner	Seropositive Partner	Seronegative Partner	Seropositive Partner
Male sex — no. (%)	986 (62)	598 (38)	1013 (64)	566 (36)	963 (61)	621 (39)
Age — no. (%)						
18–24 yr	184 (12)	268 (17)	177 (11)	287 (18)	172 (11)	273 (17)
25–34 yr	721 (46)	657 (41)	690 (44)	636 (40)	688 (43)	629 (40)
35–44 yr	480 (30)	474 (30)	498 (32)	460 (29)	513 (32)	509 (32)
≥45 yr	199 (13)	185 (12)	214 (14)	196 (12)	211 (13)	173 (11)
Education — yr						
Median	7	7	7	7	7	7
Range	4–10	4–9	4–10	4–9	4–10	4–9
Any monthly income — no. (%)	1275 (80)	1069 (67)	1236 (78)	1052 (67)	1259 (79)	1079 (68)
Any sex with outside partner in prior month — no. (%)	150 (9)	84 (5)	134 (8)	106 (7)	122 (8)	103 (7)
CD4 cell count — cells/mm ³						
Median	NA	491	NA	497	NA	499
Range	NA	370–661	NA	380–664	NA	375–663
HIV-1 plasma RNA — log ₁₀ copies/ml†						
Median	NA	3.9	NA	3.9	NA	3.9
Range	NA	3.2–4.5	NA	3.1–4.5	NA	3.2–4.5
Circumcised (men only) — no./total no. (%)	533/986 (54)	198/598 (33)	540/1013 (53)	177/566 (31)	509/963 (53)	202/621 (33)
Using contraception (women only) —	263/598 (44)	290/986 (29)	275/566 (49)	324/1013 (32)	299/621 (48)	321/963 (33)

10-12. Study Reporting

Table 1. Characteristics of the Participants at Baseline, According to Sex.*

Characteristic	Women			Men		
	Total (N = 3786)	Vaccine (N = 1893)	Placebo (N = 1893)	Total (N = 1618)	Vaccine (N = 811)	Placebo (N = 807)
Age group — no. (%)						
18–21 yr	1115 (29)	543 (29)	572 (30)	321 (20)	166 (20)	155 (19)
22–25 yr	1420 (38)	723 (38)	697 (37)	438 (27)	219 (27)	219 (27)
26–35 yr	1251 (33)	627 (33)	624 (33)	859 (53)	426 (53)	433 (54)
Body-mass index — no. (%)†						
<18.5	133 (4)	56 (3)	77 (4)	232 (14)	114 (14)	118 (15)
18.5–24	1406 (37)	725 (38)	681 (36)	1127 (70)	560 (69)	567 (70)
25–29	978 (26)	493 (26)	485 (26)	194 (12)	97 (12)	97 (12)
≥30	1269 (34)	619 (33)	650 (34)	65 (4)	40 (5)	25 (3)
Gender identity — no. (%)						
Female	3783 (100)	1892 (100)	1891 (100)	6 (<1)	5 (1)	1 (<1)
Male	2 (<1)	1 (<1)	1 (<1)	1598 (99)	801 (99)	797 (99)
Transgender female or male	1 (<1)	0	1 (<1)	10 (1)	4 (<1)	6 (1)
Gender variant	0	0	0	2 (<1)	1 (<1)	1 (<1)
Prefer not to answer	0	0	0	2 (<1)	0	2 (<1)

13. Language



Yes

- Cisgender
- Transgender
- Gender nonbinary
- Assigned female/male at birth
- Adults
- Children
- All individuals
- Pregnant people
- Childbearing potential
- Nursing
- Body parts

No (generally)

- Women
- Men
- MSM
- Born female/male
- Pregnancy (women only)
- Contraception (women only)
- Circumcision (men only)
- Gendered exams
- Mother-to-child
- Erasing GNB people



NO DATA NO MORE

"RESEARCH ON TRANSGENDER PEOPLE MUST BENEFIT TRANSGENDER PEOPLE."

-Brian Minalga, Cecilia Chung, JD Davids,
Aleks Martin, Nicole Lynn Perry, & Alic Shook



DISCUSSION



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THANK YOU

Brian Minalga

bminalga@fredhutch.org

John Meade

jmeade@avac.org