

# NO DATA NO MORE:

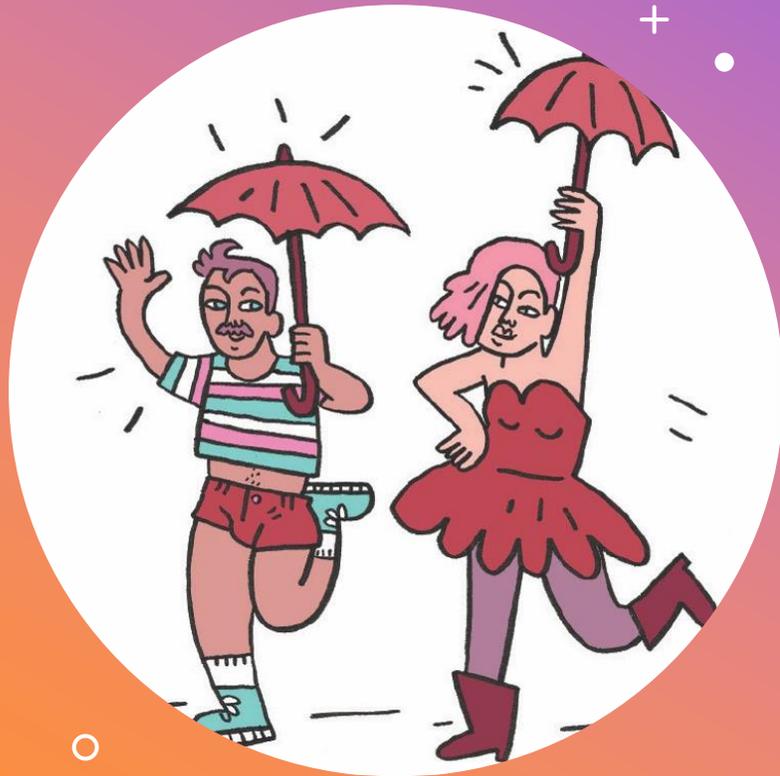
## A RESEARCH SCORECARD FOR TRANSGENDER INCLUSION



**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.





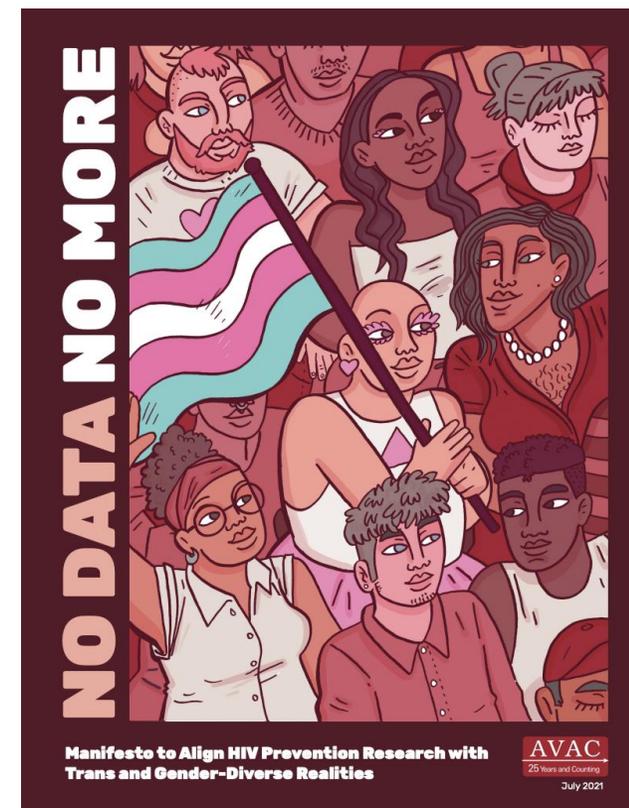
# QUIZ

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

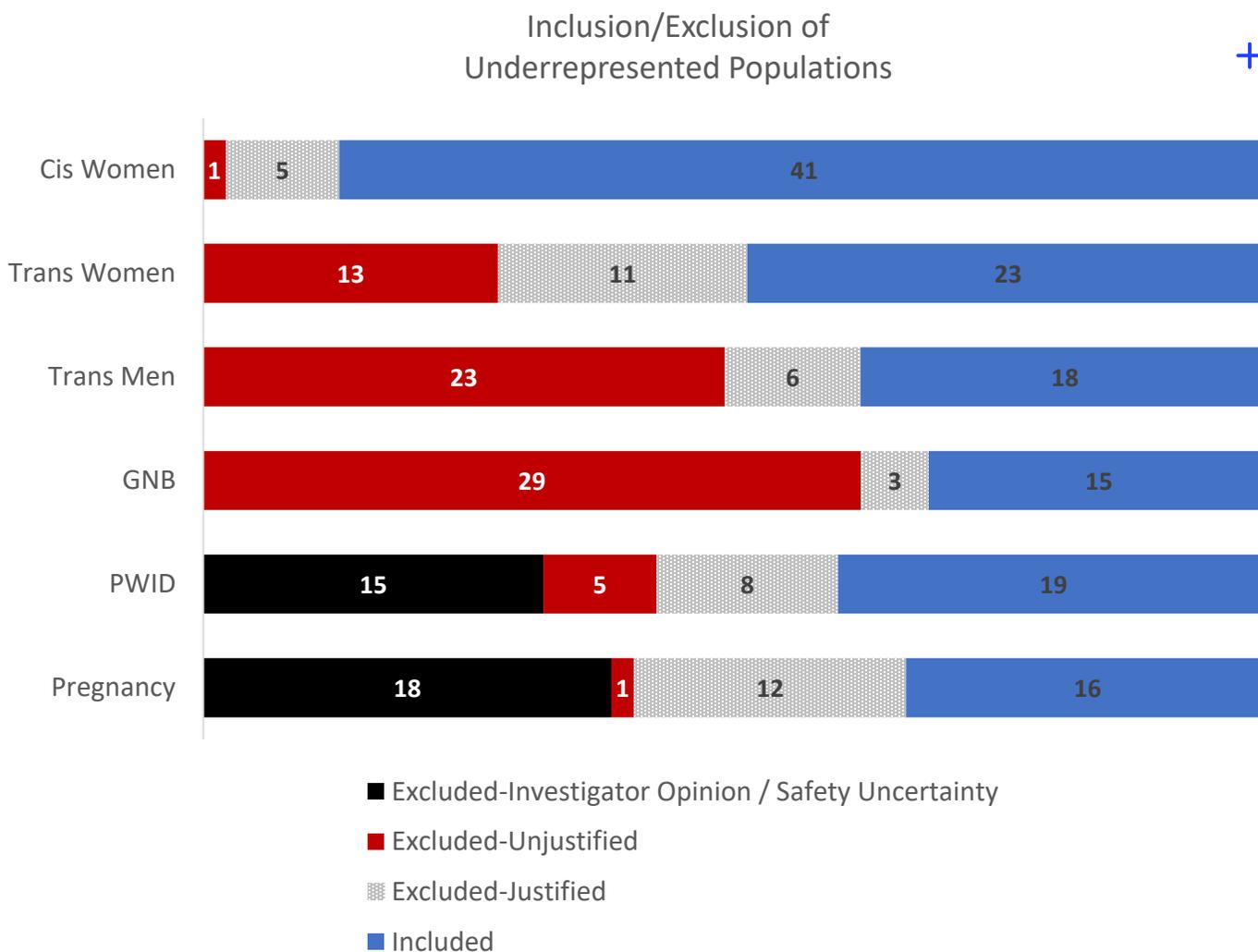
- Assessed over 30 years of milestone HIV clinical trials
  - Study protocols, publications, and records on [clinicaltrials.gov](https://clinicaltrials.gov)
  - Shout Out: Richard Jefferys (TAG)
- Based on the Representative Studies Rubric (RSR) developed at HANC





# The RSR

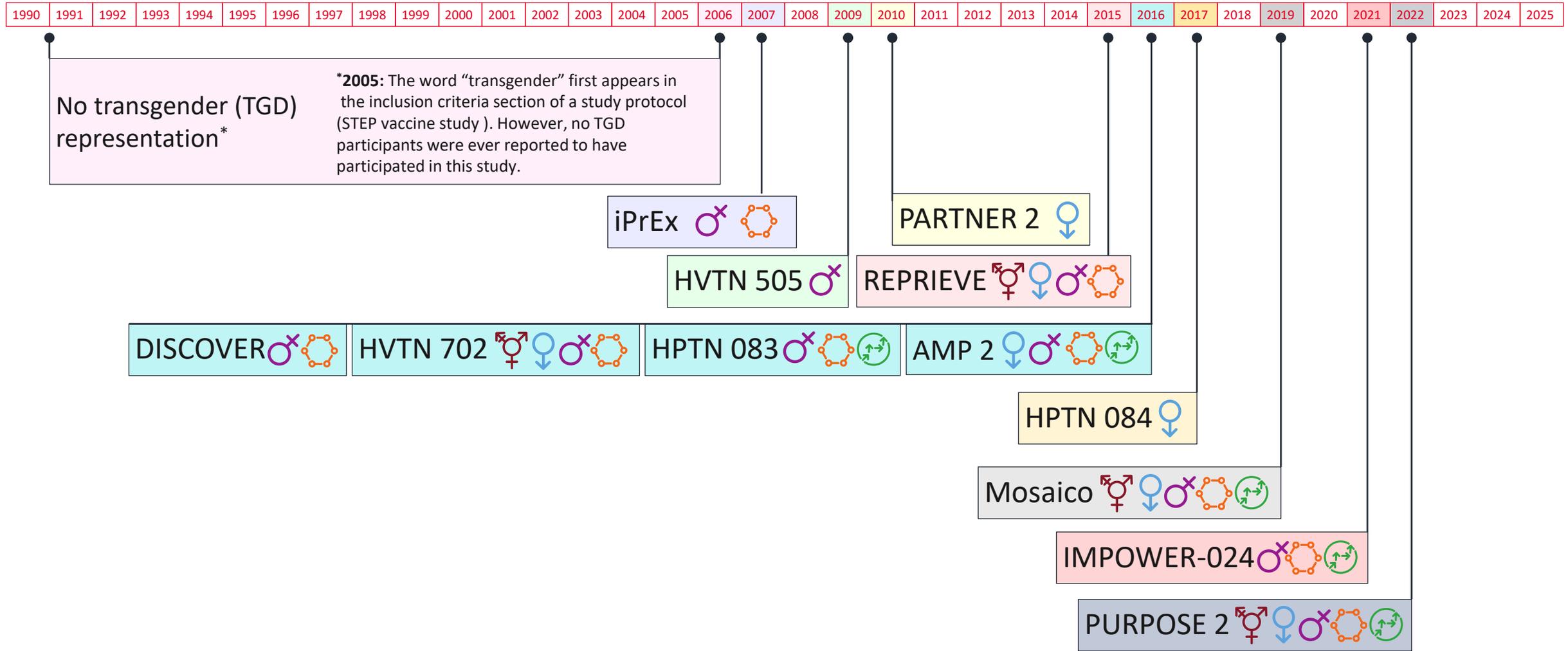
- Age
- Assigned Sex
- Drug Use
- Ethnicity
- Gender
- Pregnancy
- Race
- Language



# Scorecard Analysis: 41 Studies, 1991-present

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

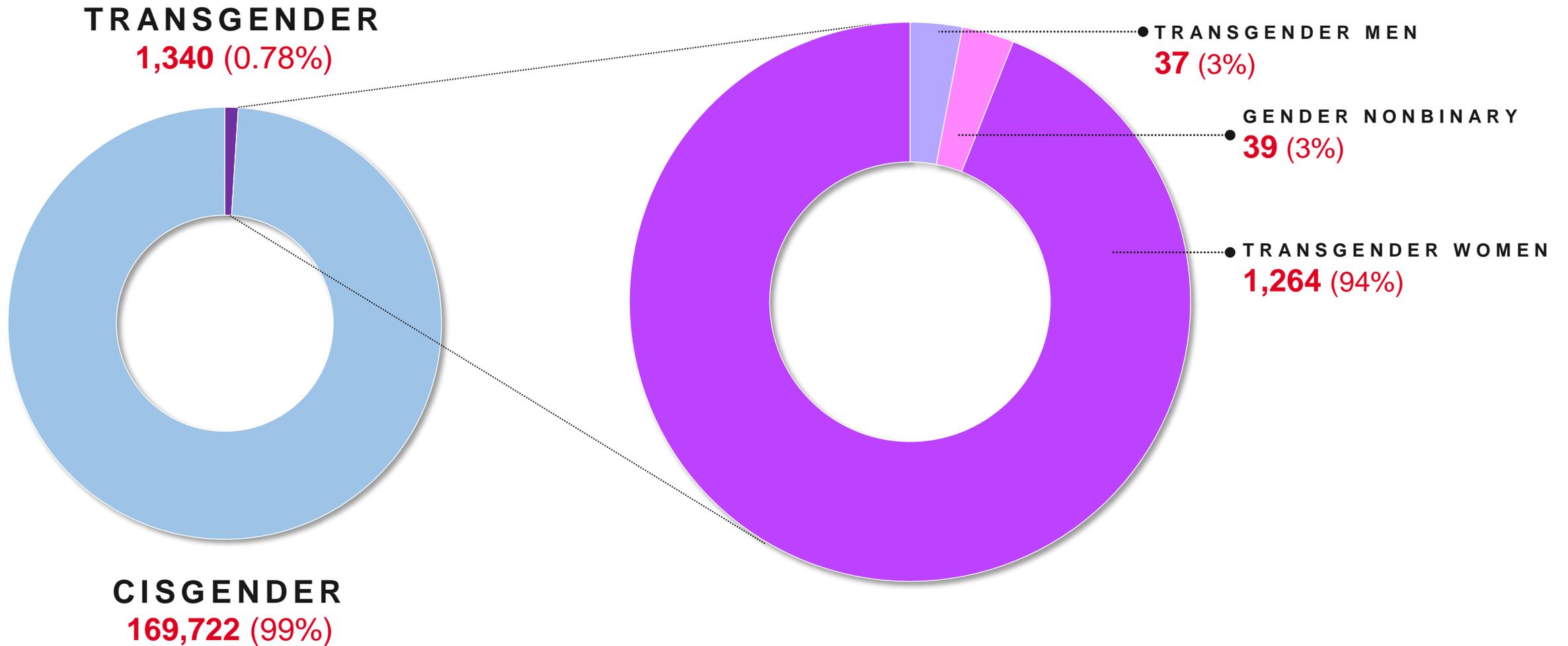
# Transgender Representation Over Time



KEY GENDER NONBINARY TRANSGENDER MEN TRANSGENDER WOMEN HORMONES MARKETING

Preliminary Findings

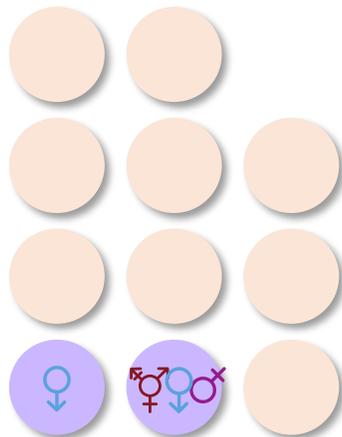
# Representation in Milestone HIV Clinical Trials



Preliminary Findings

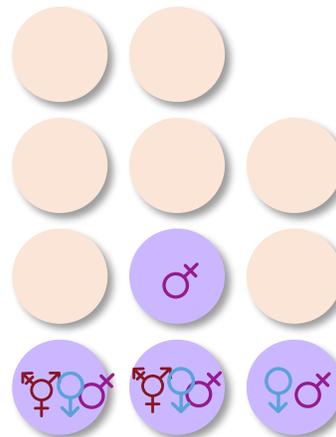
# Transgender Representation by Study Type

TREATMENT



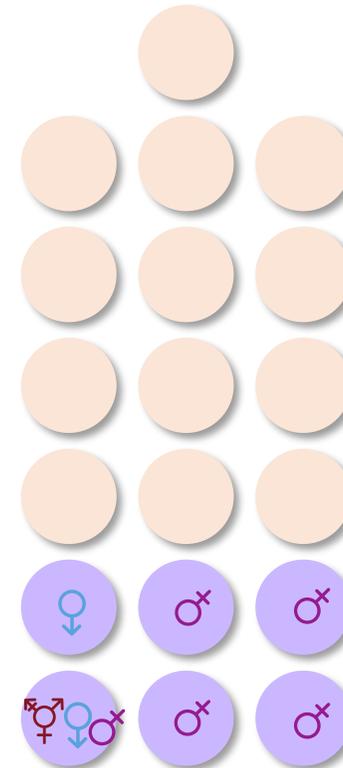
11

VACCINE/AB



11

PREP/MICROBICIDE



19

KEY

 GENDER NONBINARY

 TRANSGENDER MEN

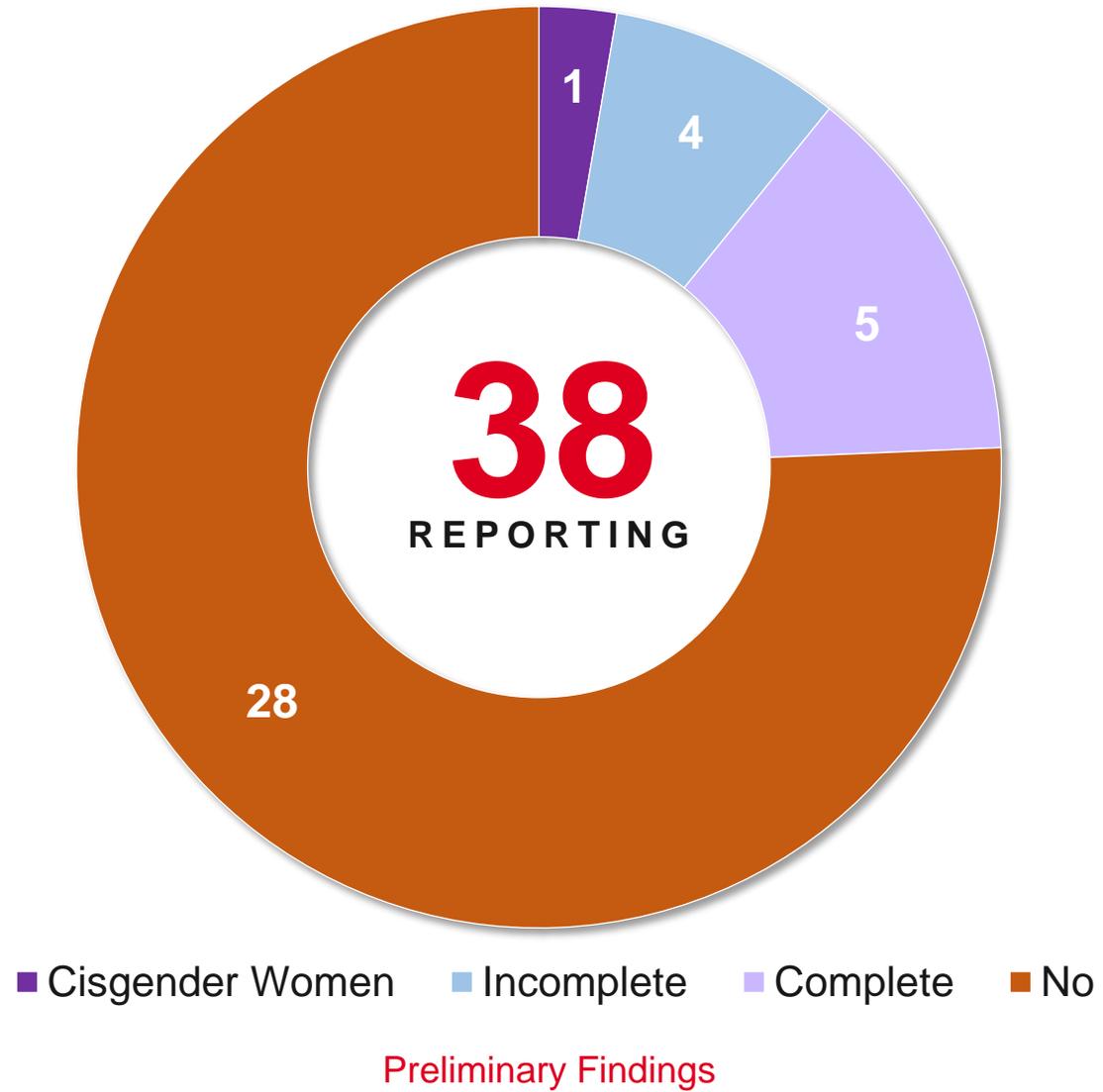
 TRANSGENDER WOMEN

 CISGENDER

Preliminary Findings

# Studies Reporting Gender

---



---

# 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  $\geq 13$  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 <sup>3</sup>						
Median	NA	491	NA	497	NA	499
Range	NA	370–661	NA	380–664	NA	375–663
HIV-1 plasma RNA — log <sub>10</sub> 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



# “RESEARCH ON TRANSGENDER PEOPLE MUST BENEFIT TRANSGENDER PEOPLE.”

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

NO DATA NO MORE



# DISCUSSION



NO DATA NO MORE



+



o

# THANK YOU

**Brian Minalga**  
bminalga@fredhutch.org

**John Meade**  
jmeade@avac.org

