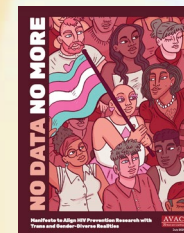


# Trans Inclusion

## Charting HIV Research into the Future

### A Manifesto and Scorecard for Advocates and Researchers



January 26, 2023



HIV prevention research - a new forum  
for advocacy on the latest

# Today's Registrants

- Belgium
- Botswana
- Brazil
- Burundi
- Canada
- Côte d'Ivoire
- Denmark
- Eswatini
- Ghana
- Holy See (Vatican City)
- India
- Italy
- Kenya
- Lesotho

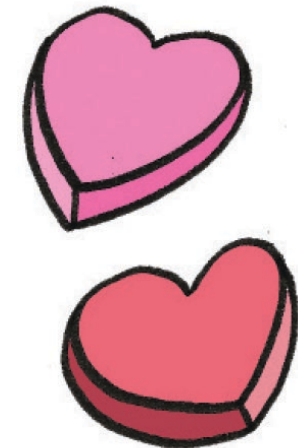


**28 countries**

**256 webinar registrants**

- Malawi
- Mexico
- Nigeria
- Peru
- Philippines
- South Africa
- Switzerland
- Thailand
- Uganda
- Ukraine
- United Kingdom
- United States
- Zambia
- Zimbabwe



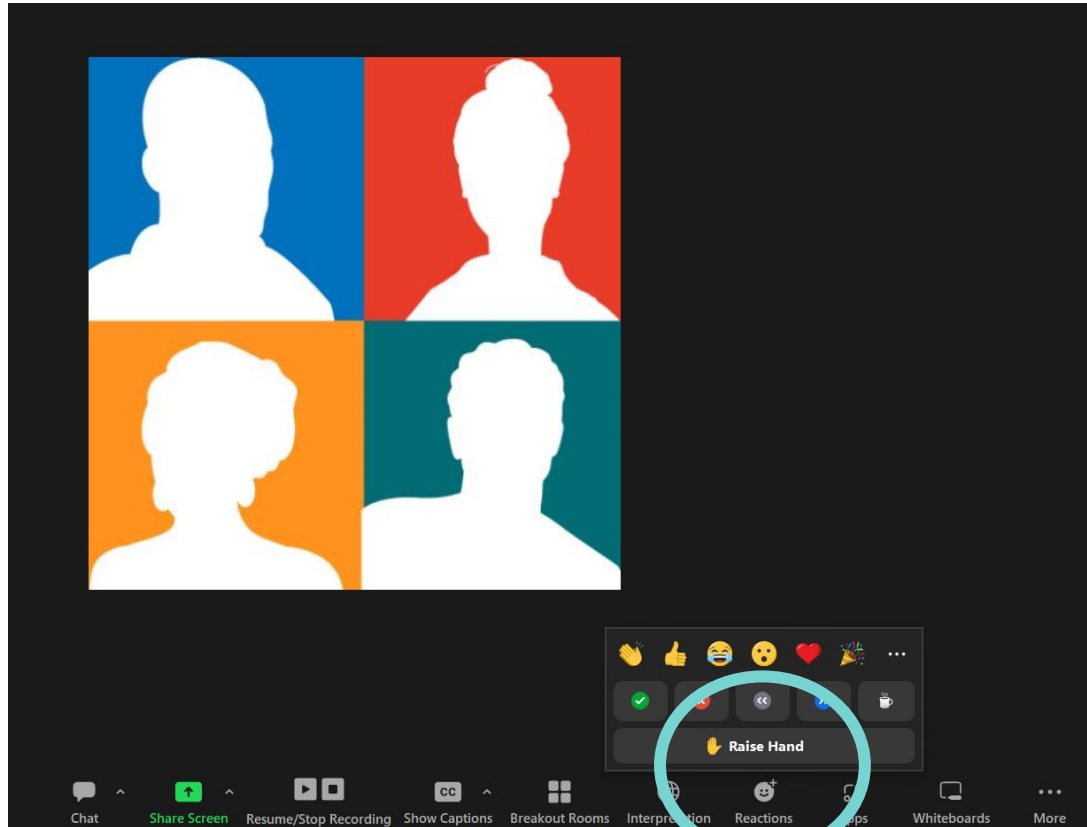



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# Webinar Logistics



- This call will be recorded. Your presence = consent.
- We are providing closed captions.
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- Let's hear your voice and see your face too. Raise hand to speak on camera.
- **We will share links to recording and slides in follow-up email.** 
- Access TCA webinar resources here:
  - [www.avac.org/choice-agenda](http://www.avac.org/choice-agenda)





# Ready, Set, CROI 2023

## Prepare for the 30th Year of CROI



February 13, 2023

Register now → [tinyurl.com/readsetcroi](https://tinyurl.com/readsetcroi)



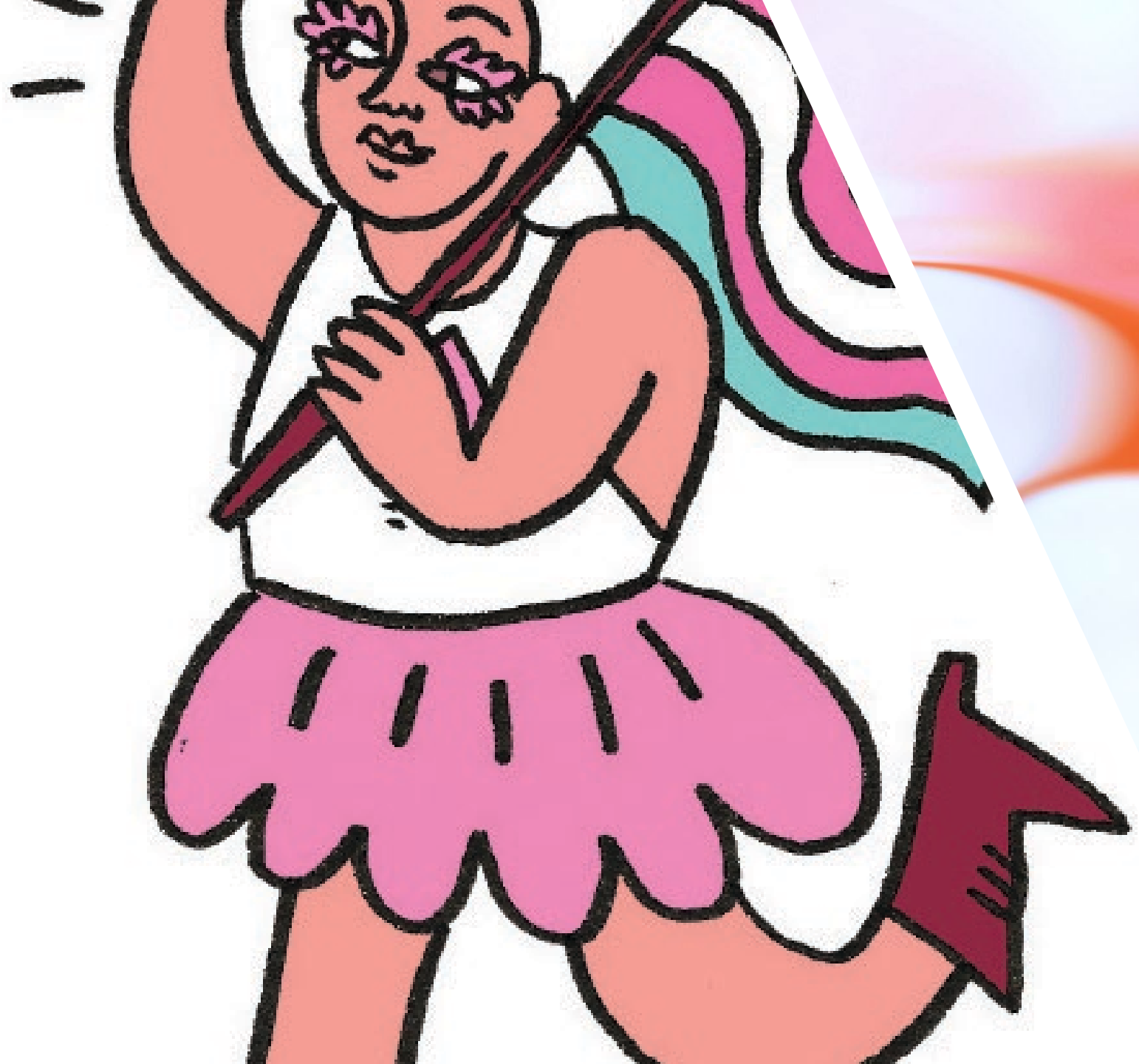
# Decolonizing Global Public Health

**What Will it Take to Dismantle  
Racism and White Supremacy?**

**February 16, 2023**

Register now → [tinyurl.com/decolonizepublichealth](https://tinyurl.com/decolonizepublichealth)









Today's Speakers

**Cindra Feurer**

**Brian Minalga**

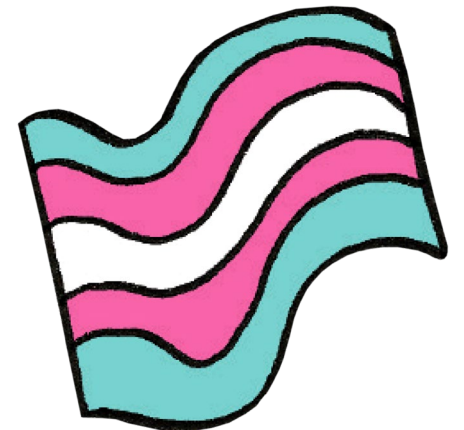
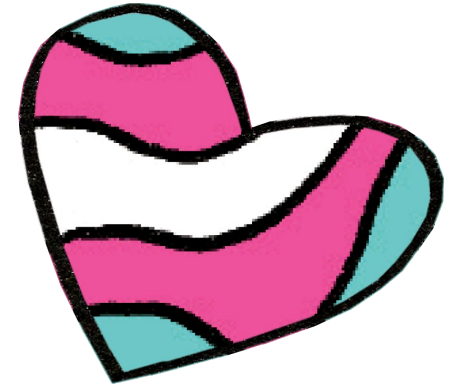
**Leigh-Ann van der Merwe**



# Trans Inclusion: Charting the Research Evolution into the Future

Cindra Feuer  
Brian Minalga  
Leigh-Ann van der Merwe

for The Choice Agenda  
January 26, 2023



# Today

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## Trans-inclusivity in Research: Paving the way for meaningful representation

- ***No Data No More: Manifesto to Align HIV Prevention Research with Trans and Gender-Diverse Realities***
  - Lived experiences
  - Gender hormone therapy and healthcare
  - Research agenda
- ***Trans-Inclusivity Scorecard: HIV efficacy studies over 30 years***
  - Results
  - A pivotal time
  - Advocacy for an inclusive future

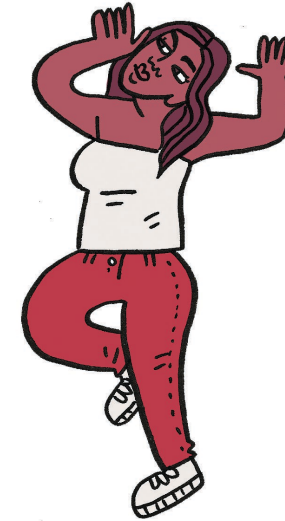


# No Data No More Manifesto, launched July 2021

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## Methodology

- Majority trans consultants
  - Max Appenroth, Cologne
  - Ricki Kgositau, Cape Town
  - JD Davids, Brooklyn
  - Imma Mugo, Cape Town
  - Rory Midhani, Berlin (artist)
  - Cindra Feuer, Brooklyn
- Technical Advisory Group: 10/11 are trans
  - Leigh-Ann van der Merwe
- Literature review, survey, interviews, workshops, external reviews, fact check





# Why the Manifesto

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## Trans and Gender Diverse People (TGD)...

- Exist! In all our glory
- Experience a disproportionate burden of HIV
  - TGW 20% HIV prevalence; 66x higher risk of infection
  - TGM 2.6% HIV prevalence; 7x higher risk of infection
  - Non binary ??????
- Surveillance data limited, especially Africa, Eastern Europe, Central Asia
- Have unique needs in the HIV response
- Are not monolithic



# Why the Manifesto

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continued

- Historically overlooked/avoided in HIV research:
  - No HIV end-point trials with primarily trans populations;
  - Trans women: sub-groups in RCTs with cis-MSM;
  - Trans men: excluded;
  - Limited implementation studies
- Increasing incidence and less likely to get tested, adhere to PrEP, maintain viral load suppression

**NO DATA NO MORE**



**Manifesto to Align HIV Prevention Research with  
Trans and Gender-Diverse Realities**

**AVAC**  
25 Years and Counting

July 2021

# Visions: A TGD Research Agenda that . . .

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## Lived experiences

- *Further identifies key drivers of HIV incidence across countries and regions*
- *Undertakes a global analysis of data gaps in trans research and health programs*
- *Addresses structural barriers to research engagement and health programs*
- *Fully considers the range of participants along the gender spectrum in clinical and implementation research*
- *Tracks epidemiological data on HIV incidence and prevalence that accurately reflects the large and growing HIV acquisition rates of TGD populations*
- *Embraces UNAIDS' top-line target for 2025 aiming for “less than 10% of countries [with] punitive legal and policy environments that deny or limit access to services”*



# Visions

## Role of gender-affirming hormone therapy (GAHT) and healthcare



- ***Further explores how GAHT might affect HIV susceptibility***
- ***Further studies the drug-drug interactions between hormone therapies and antiretroviral therapy***
- ***Ensures all new PrEP compounds in development undergo drug-drug interaction studies with feminizing and masculinizing hormones***
  - ***Specifically, addresses the urgent efficacy and safety questions of on-demand oral PrEP for TGD on GAHT***
- ***Integrated gender-affirming care across the HIV care and prevention continuum (UNAIDS 2025 target) as well as research settings***

# Visions

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## HIV prevention research

- ***Disaggregates data by gender identity***
- ***Provides inclusion criteria for trans people (across the gender spectrum) in clinical trials and reports how gender is defined by the study protocol***
  - ***Adheres to the NIAID HIV Language Guide***
  - ***Reports inadequate trans representation in enrollment data in limitations of the research***
- ***Explicitly includes trans men and other assigned female at birth (AFAB) trans people in the eligibility criteria of all HIV clinical trials***
- ***The research site is populated by employees who represent the community and can competently offer trauma-informed care***

# And So Much More

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*No Data No More* Manifesto also includes...

- More than 2 dozen visions and indicators
- A summary of drug-drug interactions between PrEP and GAHT
- Additional references and literature
- Gorgeous art



# The Manifesto, Advocacy in Practice

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Released, IAS July 2021

- Conduct more than 20 “Roadshow Dialogues” with civil society, pharma, government research entities, NGOs, regulatory authorities, and conferences.
- TG ROAR 2.0 relaunch: AVAC’s partner advocacy program for trans research inclusivity and gender justice
- Scorecard for Trans-Inclusive Research: an analysis, based on No Data No More Manifesto visions
  - Debut findings, today
  - Advocacy Scorecard template, Q1 2023
  - Publication, 2023





*Manifesting* the Vision  
No Data No More

Questions?

# Scorecard

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## Objectives/Methodology

- To synthesize the Manifesto's visions into a series of scoreable indicators of TGD representation in HIV clinical trials
- To assess milestone HIV studies from the early epidemic to the present for TGD representation
  - Review study protocols, study publications, and [clinicaltrials.gov](http://clinicaltrials.gov)
- To promote TGD-inclusive study design and advocacy by providing the HIV field with a scorecard advocacy tool

*\* Shout out of thanks to Richard Jefferys, Basic Science Vaccines and Cure Director at TAG, public scientist, HIV historian and famed DJ*

# Scorecard

## 41 Milestone 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)                  |                                   |

# Scorecard Indicators

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## Did the study include the following

- Trans participants
  - gender nonbinary
  - trans men
  - trans women
- TGD Inclusive systems
  - enrollment goals
  - disaggregated data
  - outreach/marketing
  - staff
  - partnerships
  - competent research site selection
- Gender-affirming hormone therapy (GAHT): safety, efficacy and/or drug-drug interactions
- Two-step reporting: sex assigned at birth and gender identity
- Language: adhered to best practices in protocol and publication

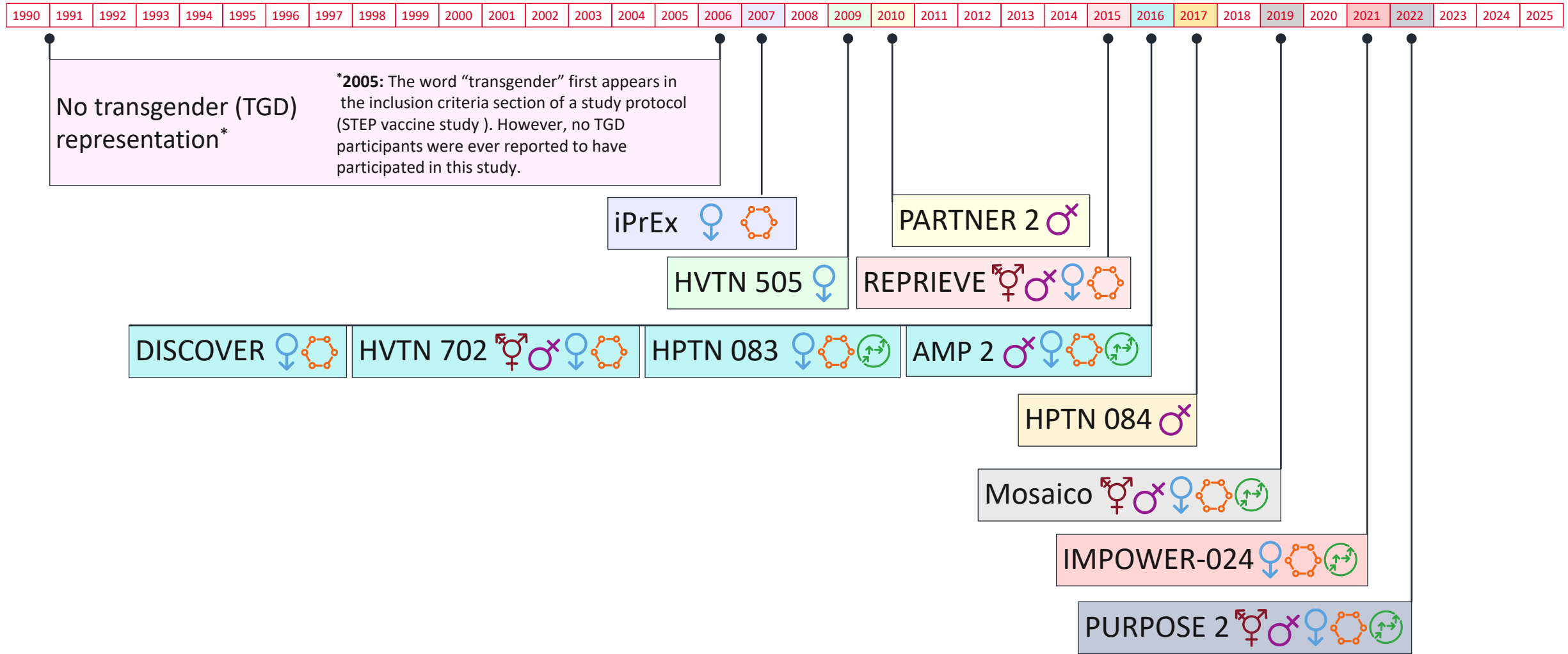


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# Preliminary Scorecard Results



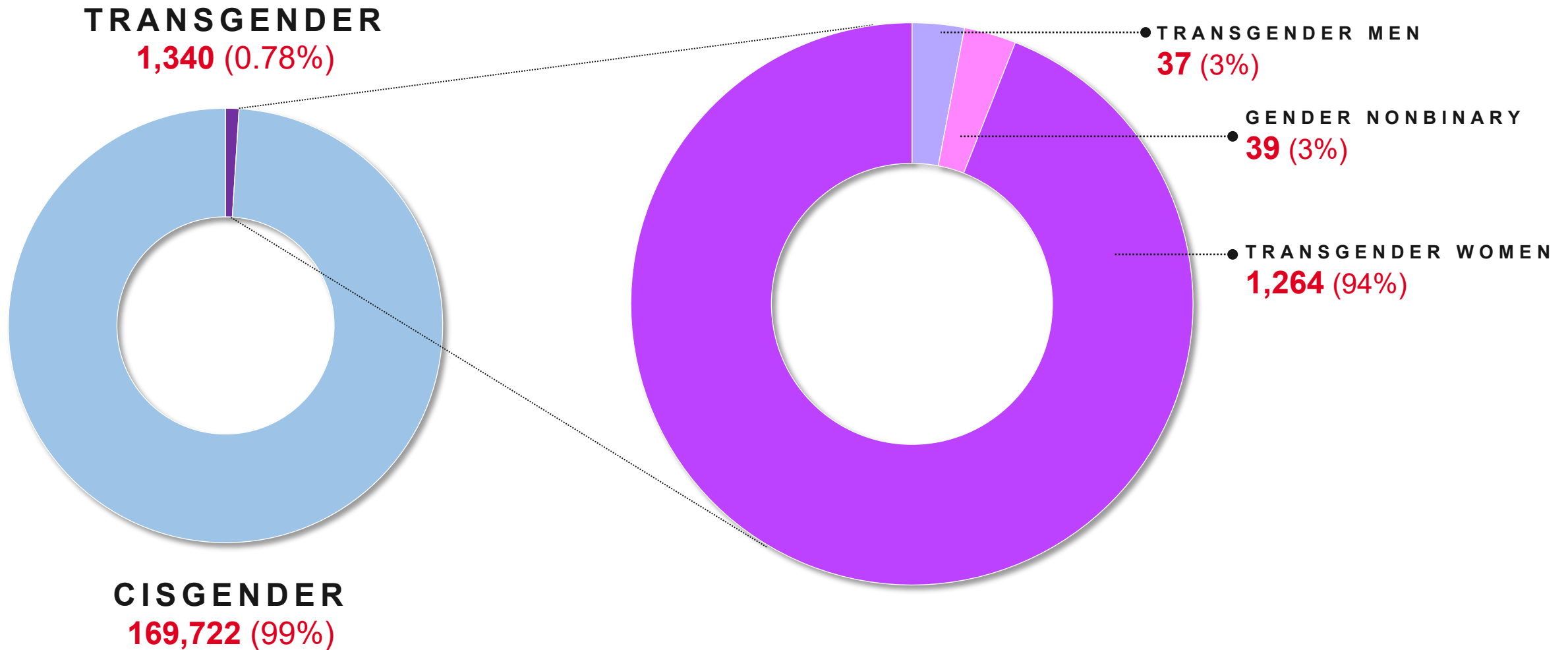
# Transgender Representation Over Time



KEY GENDER NONBINARY TRANSGENDER MEN TRANSGENDER WOMEN HORMONES MARKETING

Preliminary Findings

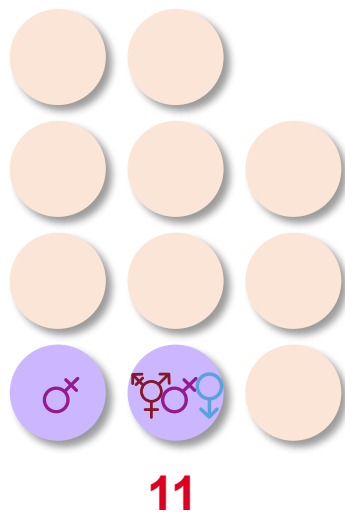
# Representation in Milestone HIV Clinical Trials



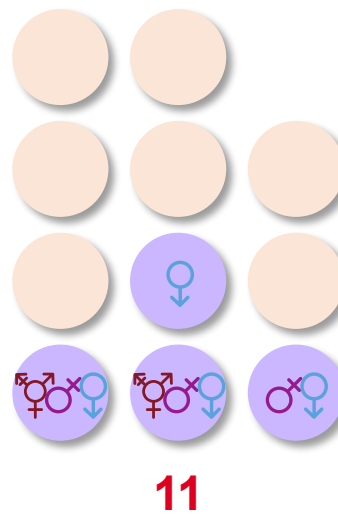
Preliminary Findings

# Transgender Representation by Study Type

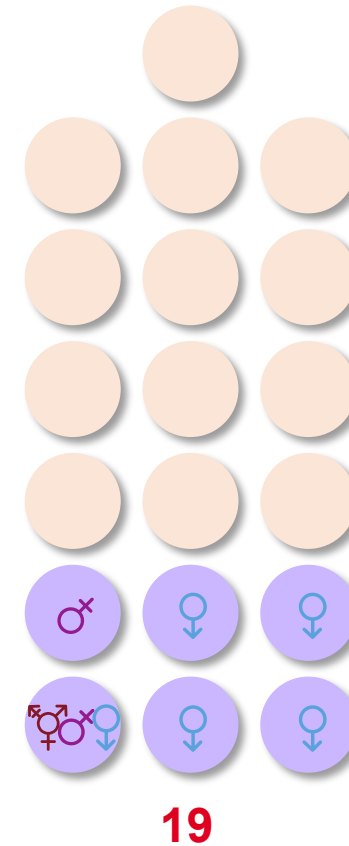
TREATMENT



VACCINE/AB



PREP/MICROBICIDE



KEY

 GENDER NONBINARY

 TRANSGENDER MEN

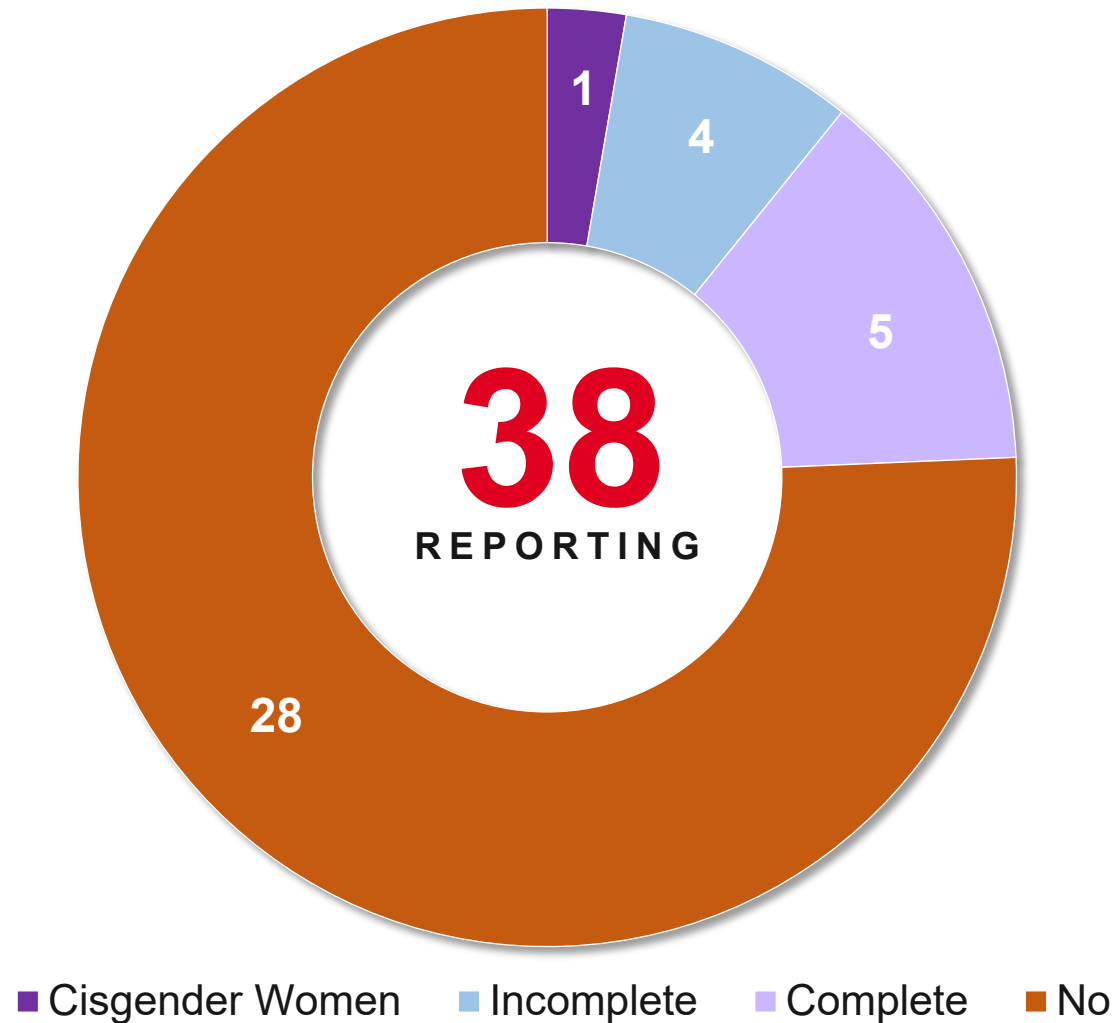
 TRANSGENDER WOMEN

 CISGENDER

Preliminary Findings

# Studies Reporting Gender

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Preliminary Findings

# Quiz!

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Which study scored highest on how it reported its results?

- A. PopART (HPTN 071)
- B. Partners PrEP
- C. Uhambo (HVTN 702)

And why?



# A. PopART (HPTN 071)

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

| Characteristic                  | Group A<br>(N = 12,671)              | Group B<br>(N = 13,404) | Group C<br>(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)          |

# B. Partners PrEP

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

| Characteristic  | TDF<br>(N=1584 couples) |                      | TDF-FTC<br>(N=1579 couples) |                      | Placebo<br>(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)         |

# C. HVTN 702

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

| Characteristic             | Women             |                     |                     | Men               |                    |                    |
|----------------------------|-------------------|---------------------|---------------------|-------------------|--------------------|--------------------|
|                            | Total<br>(N=3786) | Vaccine<br>(N=1893) | Placebo<br>(N=1893) | Total<br>(N=1618) | Vaccine<br>(N=811) | Placebo<br>(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)             |

# Quiz!

---

Which study scored highest on how it reported its results?

- A. PopART (HPTN 071)
- B. Partners PrEP
- C. Uhambo (HVTN 702)

And why?

# Scorecard

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## Interim Conclusions

- Since 1991, **TGD people made up less than 1% (1,340 / 171,062) of participants** in 41 key HIV clinical trials.
  - Vast majority were trans women. Trans men and GNB only 3%, respectively.
- First reported trans enrollment was not until 2007 (iPrEx).
- In total, 29% (12 / 41) of the trials analyzed included any TGD participants
- Only three trials explicitly justified trans exclusion (AMP 1, IMPOWER 22, PURPOSE 1)
- Only four trials set trans enrollment goals (HPTN 083, 10%; PURPOSE 2, 20%; IMPOWER 24, 100/1500; and Mosaico, 10%)



# Scorecard

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## Interim Conclusions continued

- Only five studies included TGD people in outreach, marketing, and recruitment strategies (HVTN 706, HVTN 704, HPTN 083, IMPOWER 24, PURPOSE 2)
- Only eight studies accounted for gender-affirming hormone therapy as a study variable—eligibility, safety, efficacy, and/or drug-drug interactions (REPRIEVE, HVTN 702, AMP 2, iPrEx, DISCOVER, HPTN 083, Mosaico, and PURPOSE 2)
- Only 8 study protocols clearly and correctly defined the study population in terms of gender and sex (PARTNER 2, Mosaico, DISCOVER, HPTN 083, IMPOWER 22, IMPOWER 24, PURPOSE 1 and PURPOSE 2)
- Only 6 studies clearly and correctly *reported* the gender and sex of participants in primary publications of study results.
- TGD involvement—partnership, hiring, site selection: Little information was available but one study satisfies all categories (PURPOSE 2)

# Into the Future

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## Sustaining the recent trend for meaningful TGD inclusion

- Advocates and researchers accelerate the inclusivity trend
  - Provide research jobs to the TGD community
  - Representation in development of research and methods before funding
  - Equitable budgeting with TGD community
  - Sustainable, integration of research activities into clinical/service sites
  - Sustainable demonstration studies as service opportunity
  - Optimize partnerships beyond CABs
  - Transparent and broad communication at every stage: research purpose, data usage; preliminary findings, full results
  - Stop marginalizing trans masculine and nonbinary people—understand risks, sexual partners and activities
  - Standardize HIV surveillance data
  - National level recognition of gender diversity

Thanks to: Klein A, Golub SA. Ethical HIV research with transgender and non-binary communities in the United States. *J Int AIDS Soc.* 2022;**25**(S5):e25971

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## No Data No More Manifesto

*“Trans people don’t stand in the way of epidemic control,  
we are a solution.”*

—JD Davids

Join us!

[tgagenda@avac.org](mailto:tgagenda@avac.org)



*Manifesting the Vision*  
No Data No More

Discussion

