The question

What is the data on women's representation in clinical trials for FDA-approved drugs?

Are women still under represented in clinical trials?

The finding

In 67% of pivotal trials, women's enrollment met or exceeded their share of the disease burden.

Zaaijer, S., Groen, S.C. Sex representation in trials relative to indication-specific disease burden in FDA-approved drugs (2015–2023). Nat Commun 17, 6962 (2026).

The study

Pivotal Interventional Trials

These are usually phase 3 trials that provide decisive proof of the safety and efficacy of a treatment.

Details of the study discussed in this paper:

9 years

2015 — *2023*

218 Pivotal trials

195 FDA approved drugs

98 Diseases

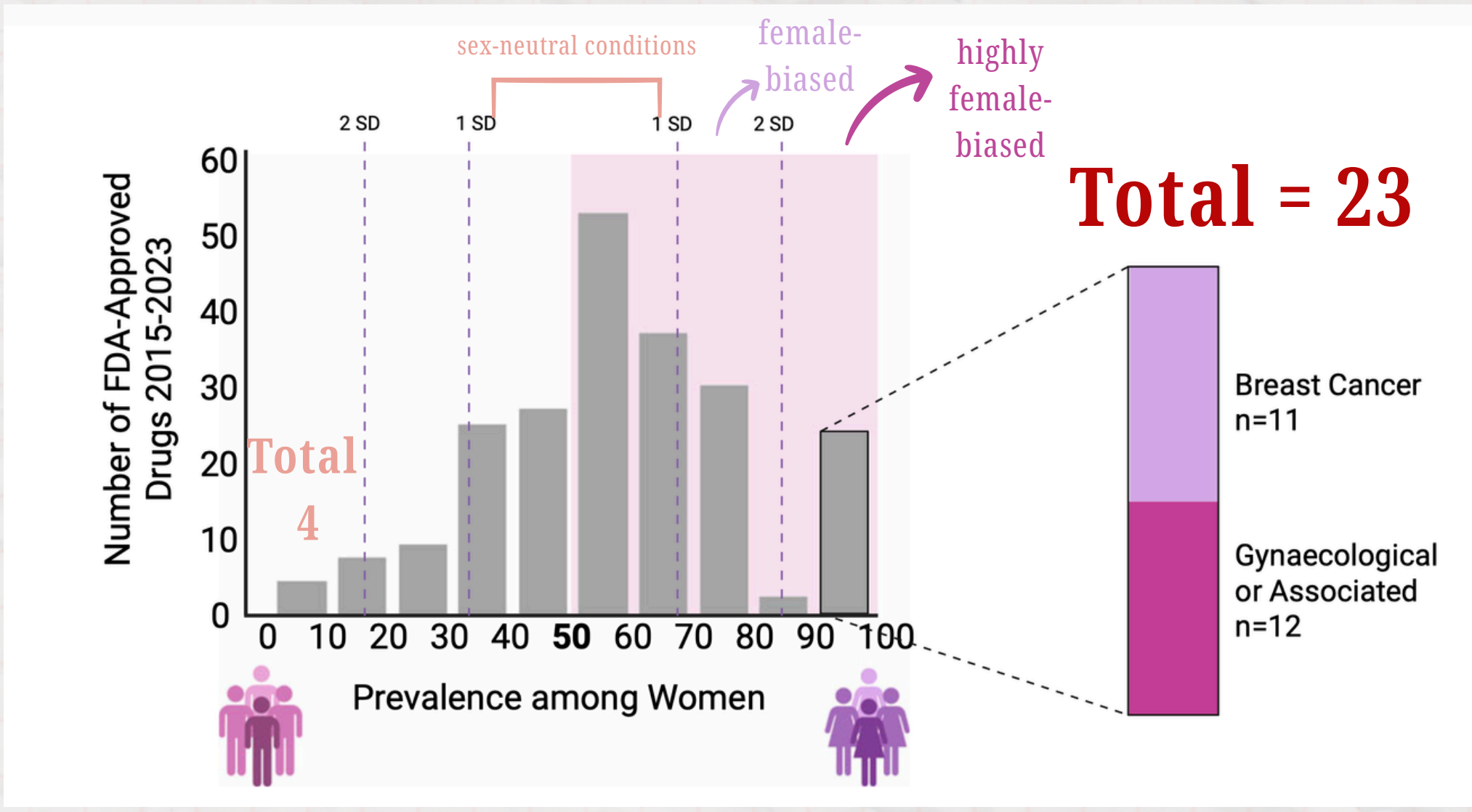
14 Therapeutic areas

The finding: Sex-specific diseases

Analysis on FDA approved drugs

Women-specific indications received **5.5 times higher FDA approval** than male-specific indications

Out of 195 FDA approved drugs:



The finding: More complicated

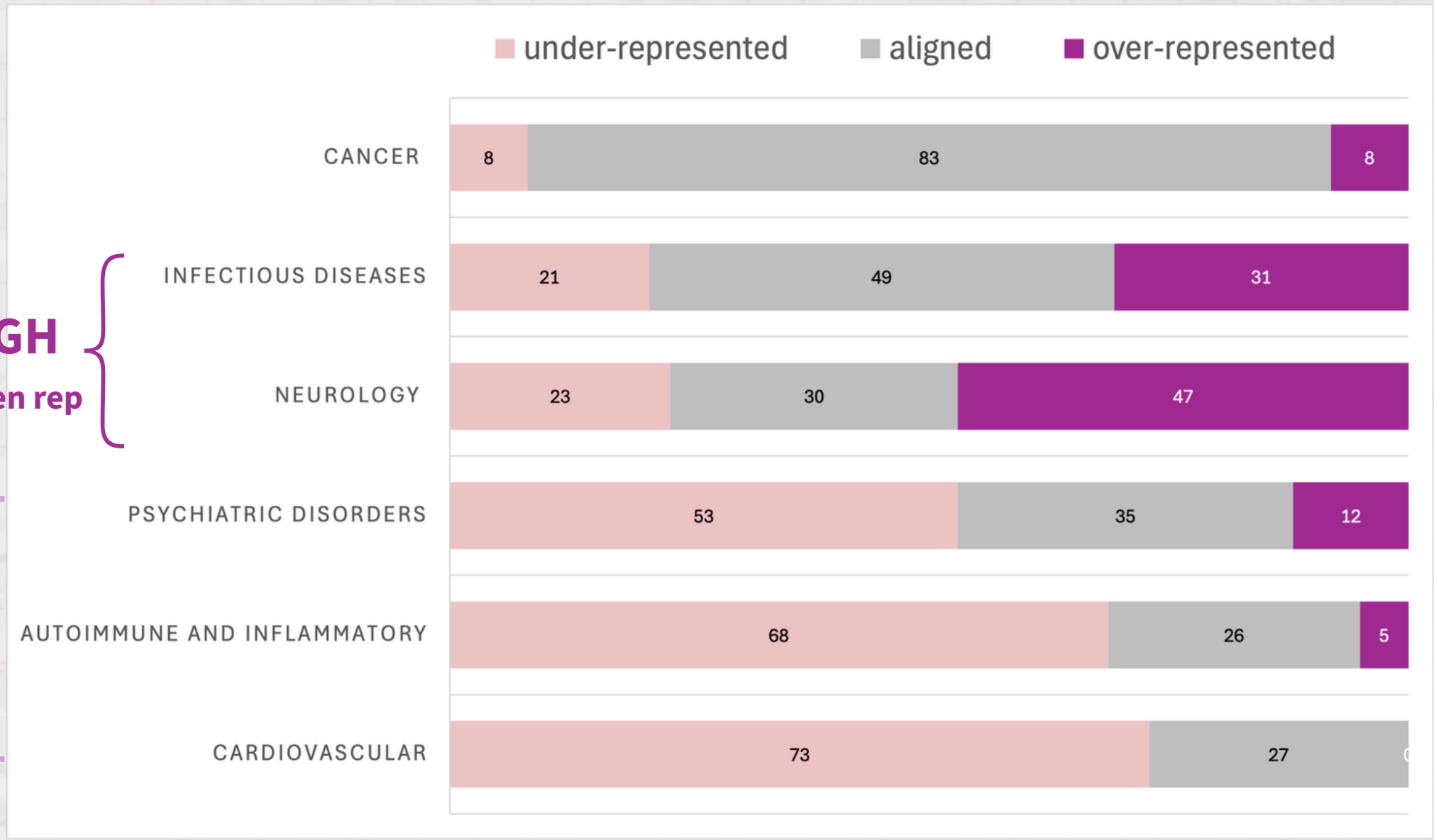
Comparing prevalence vs trial enrollment

Disease	Prevalence in women	Women enrollment	Trend
Urinary Tract Infections	76 %	50 %	Under
Migraine	68.5 %	84 - 89 %	Over
Osteoporosis	82 %	100 %	Over

→ Although 67% of trials met or exceeded women representation, the numbers are **not uniform across diseases**

The finding

Female representation in therapeutic areas



In **cancer**, structural (*diagnostics and objective end-points)* and biological factors (*higher patient age beyond reproductive age*) align to **support more proportionate representation**

The challenges

WHY are women underrepresented in some trials?

1

Calibrated on men

- Symptoms and diagnostic frameworks were historically defined from male patients
- Examples: cardiovascular diseases and schizophrenia

2

Reproductive age-related caution

- Biological factors like fetal risks, interactions with contraceptives, and hormone variations lead to exclusion of women from trials.
- Examples: psoriasis

3

Subjective endpoints

- Using clinician- and patient reported outcomes rather than biological markers can increase variability in data (or noise)
- Examples: Neurological and psychiatric disorders

→ 67% matching/overrepresentation was most common in therapeutic areas that benefit from precise diagnostics, objective endpoints and older participant populations.

→ **Without addressing these barriers, further improvement in women's enrollment may remain limited.**

The solutions

HOW can we solve these issues?

1 Diagnostic Challenges

- **More research and investment** into new and better molecular diagnostics
- Capturing diverse symptoms using **AI tools, wearables, medical devices, and patient-centered apps**

2 Improving the inclusion of women in reproductive age

- Use of **human cell-based assays** to reproductive toxicity
- Routine **capture of menopausal status, contraceptive use, menstrual cycle**, etc

3 Improving endpoints

- Make a**djustments to trial design** by pre-specifying heterogeneity analyses and sex-by-treatment interactions.

Conclusions

→ Overall, there has been **so much progress** in women's enrollment in clinical trials

→ **But unless challenges are addressed, many therapeutic areas will remain under-represented**