

Advancing NIH Policy to Consider Sex As a Biological Variable

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**OFFICE OF RESEARCH
ON WOMEN'S HEALTH**

*Advancing the Health of
Women Through Science*



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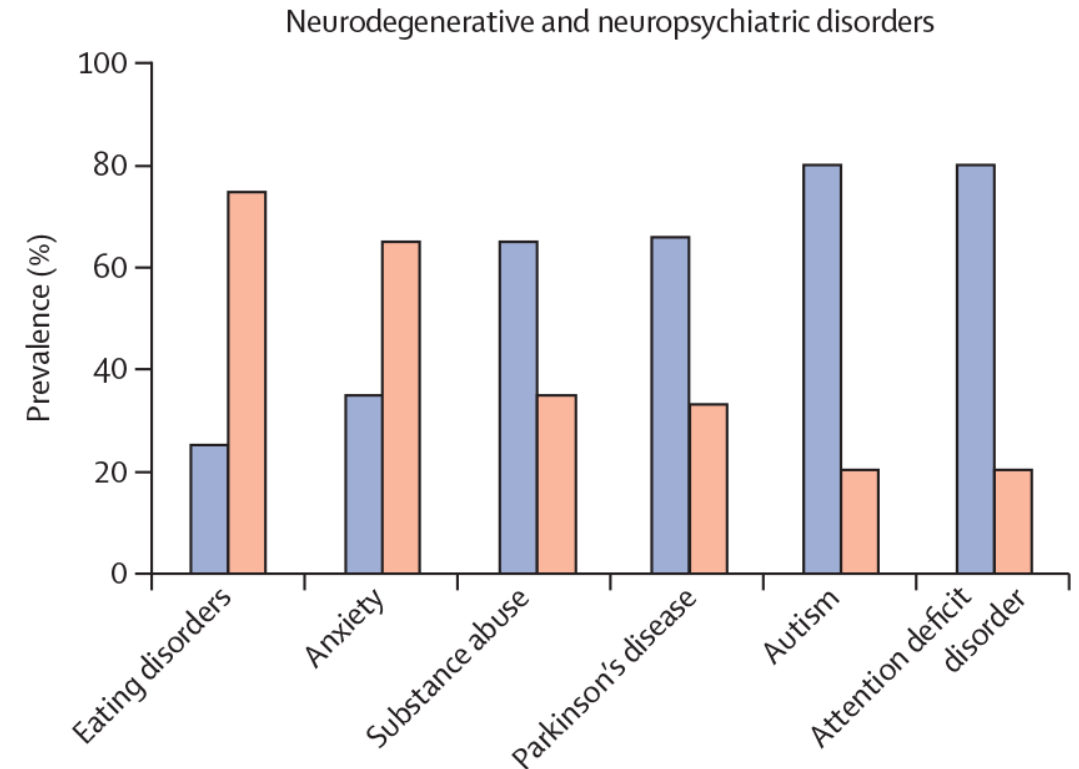
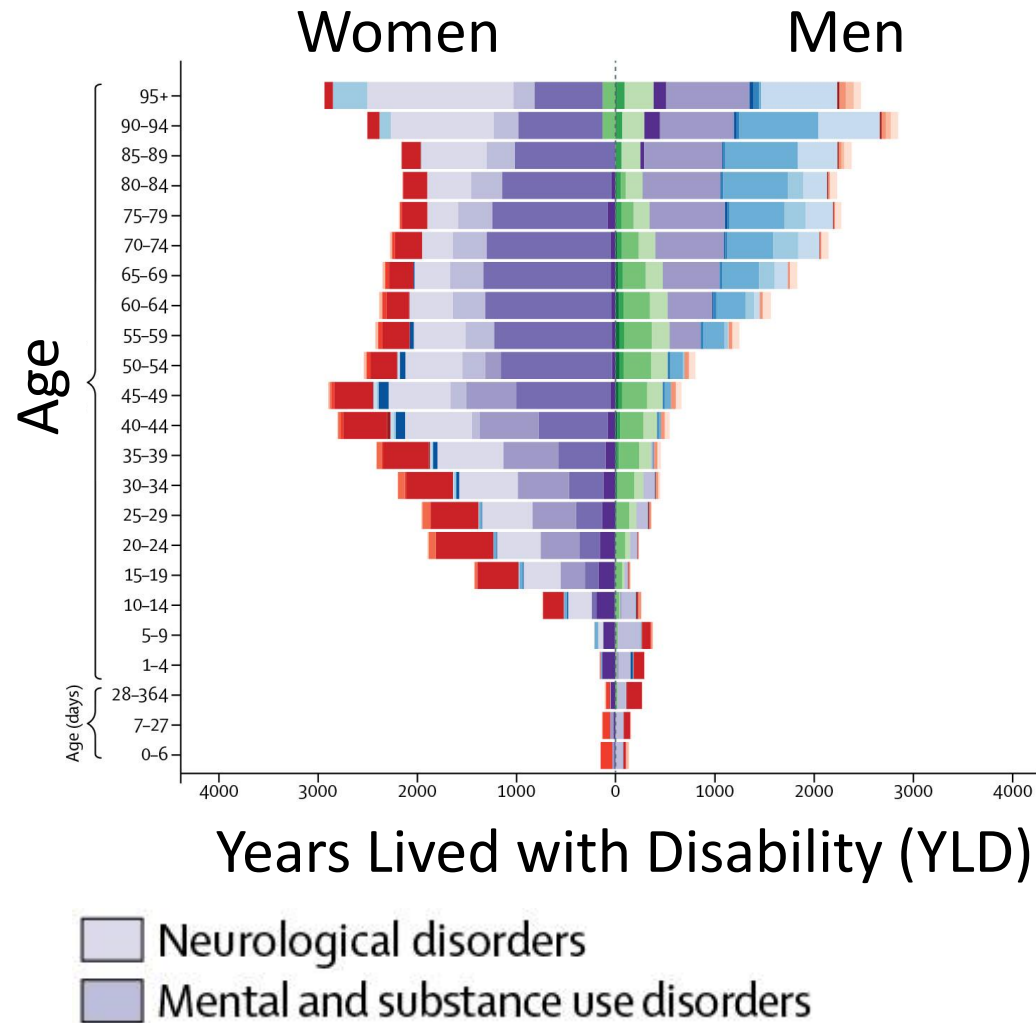
 nih.gov/women

#ResearchForWomen



NIH National Institutes of Health
Office of Research on Women's Health

Neurological and mental disorders are diagnosed more frequently in women



ORWH Mission



Enhance and expand women's health research



Include women and minority groups in clinical research



Promote career advancement for women in biomedical careers



NIH Vision



Sex and gender integrated into biomedical research



Every woman receives evidence-based care



Women in science careers reach their full potential

2019 - 2023

ADVANCING SCIENCE FOR THE HEALTH OF WOMEN

Trans-NIH Strategic Plan for
Women's Health Research



Goal 1



Goal 2



Goal 3



Goal 4



Goal 5



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“NIH expects that sex as a biological variable will be factored into research designs, analyses and reporting in vertebrate animal and human studies.”

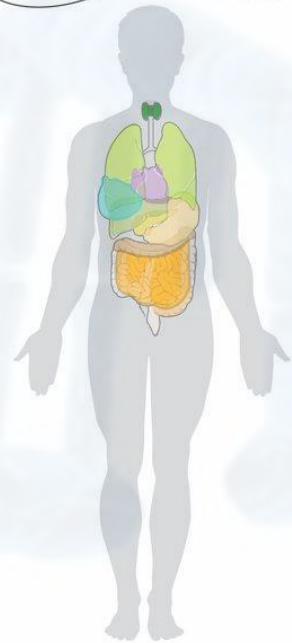
NIH received 54,903 research project grant applications in FY2019 (funded 11,035)



SABV

Sex affects gene expression and genetic regulation across tissues

Sex biases in biological processes and pathways



Male

Sex-biased eQTL
mediation by cellular
abundances

Sex biases in transcriptional regulation



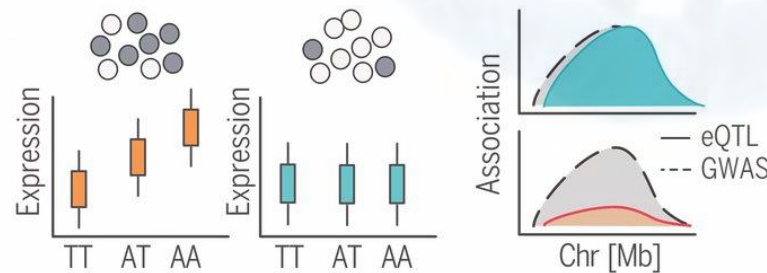
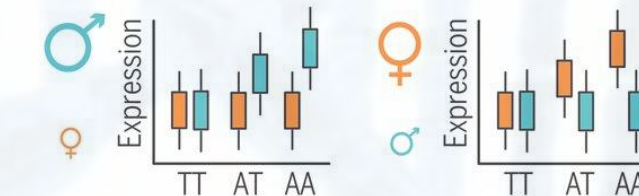
Female

Sex biases
in gene-trait
association

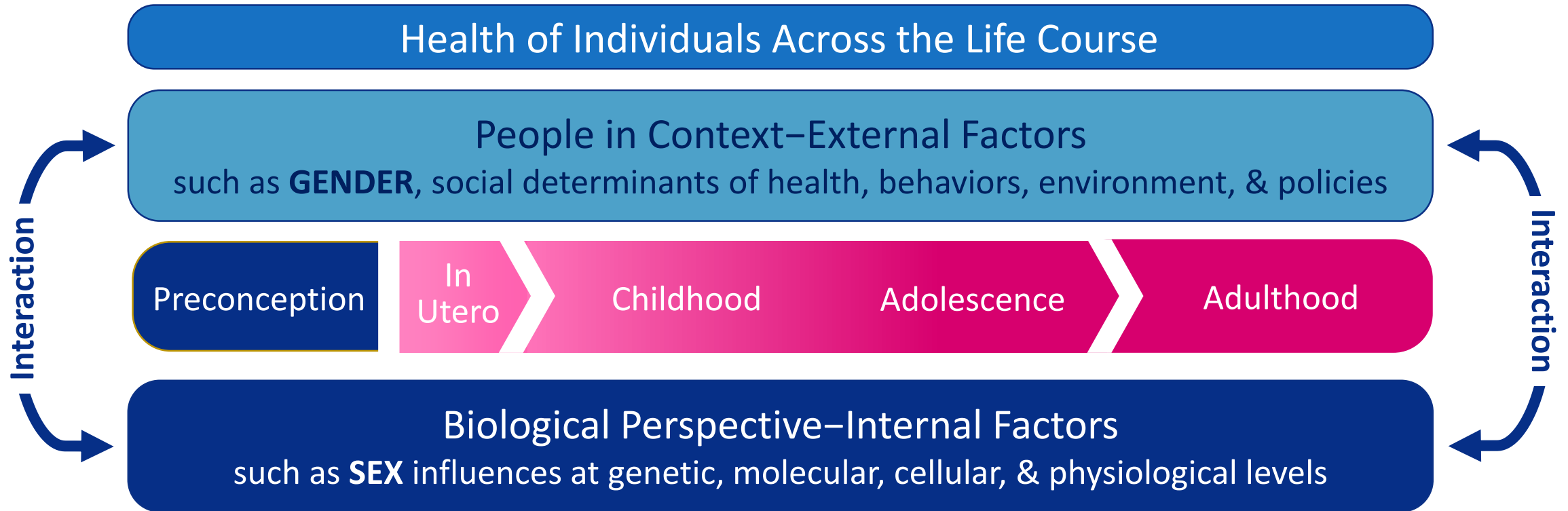
Sex-biased gene expression



Sex-biased eQTLs



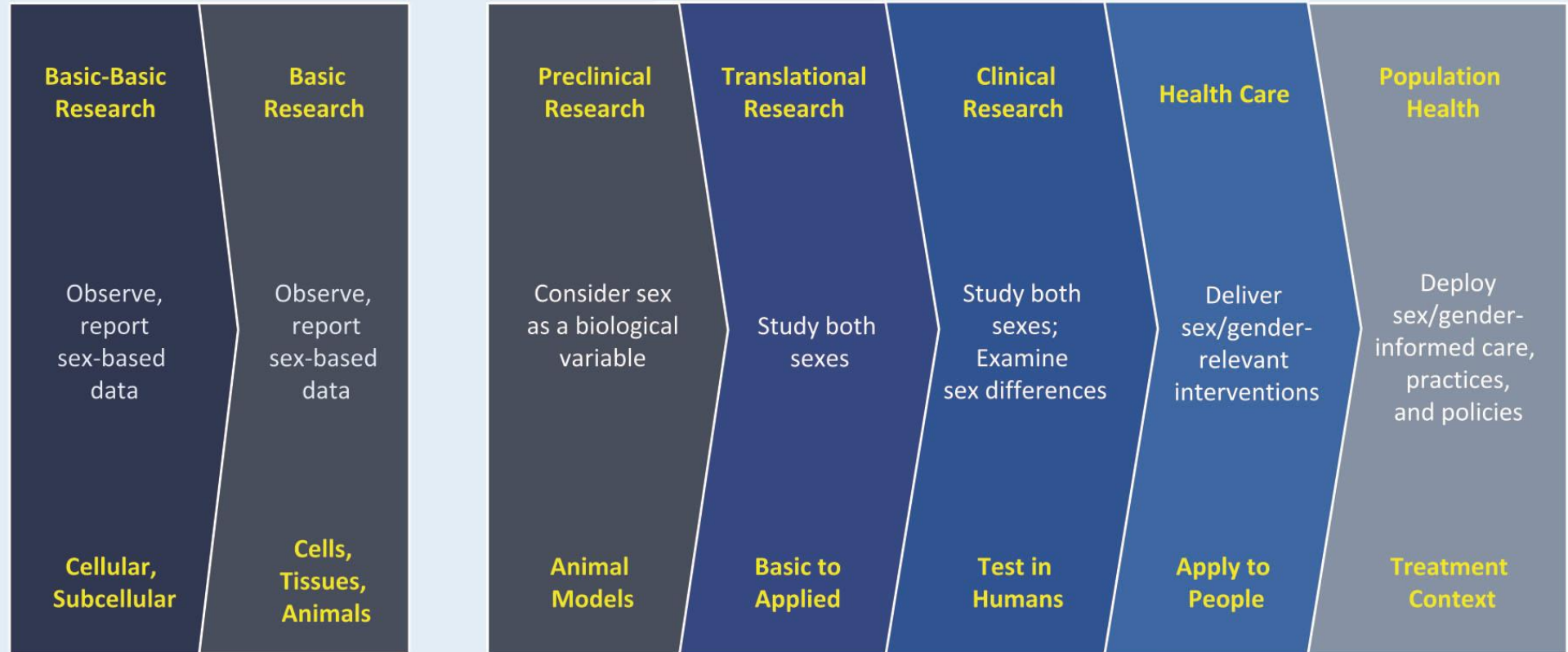
Health must be studied within a framework that includes both biology and context



Discovery

Turning Discovery into Health

REPORTING ESSENTIAL THROUGHOUT

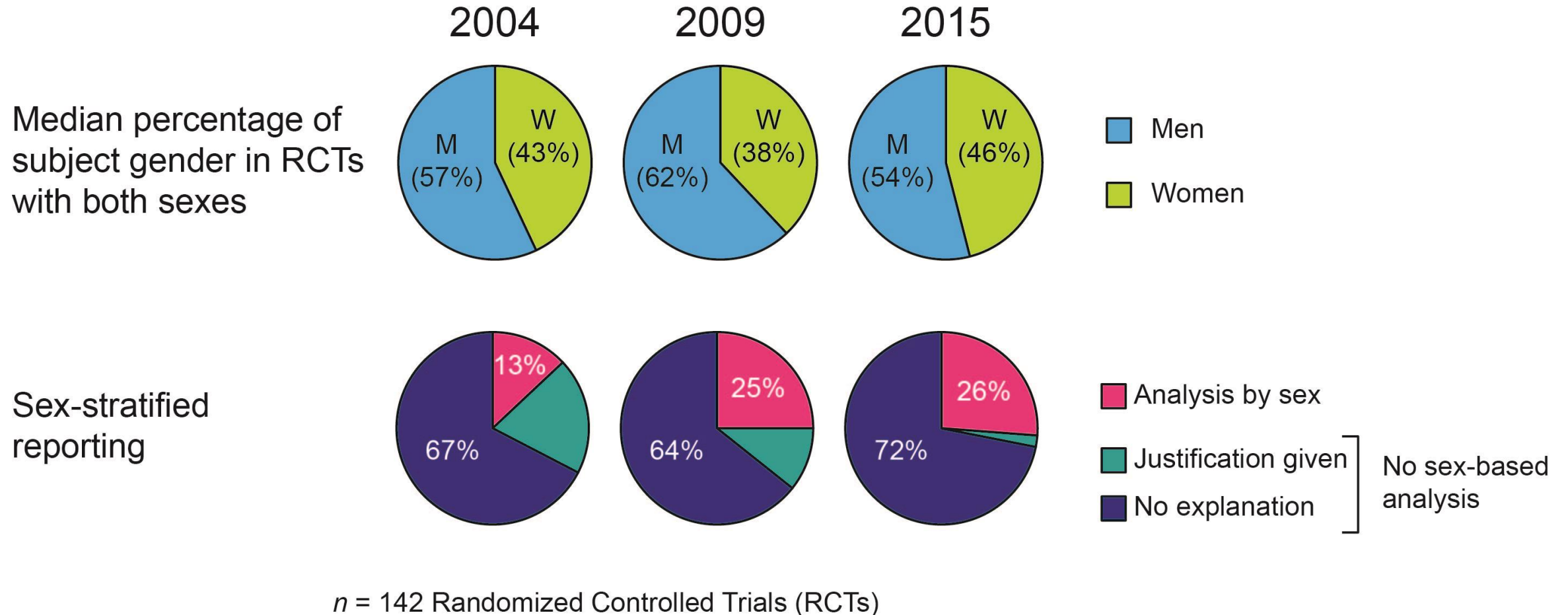


Less data

More data

SABV is an integrating approach for studies across the biomedical research continuum

Sex-specific results reporting is essential to achieve the full benefit of SABV



Strategic Goal 1

Research

- 1.1 Discover **basic biological differences** between females & males
- 1.2 Investigate the **influence of sex/gender on disease**
- 1.3 Investigate effects of **exposure** on disease outcomes
- 1.4 Promote research on sex/gender and the **mind-body** connection

ORWH developed programs to investigate sex and gender influences on health

- Specialized Centers of Research Excellence (SCORE)
 - Investigate the role of sex differences on the health of women
 - Develop standards for consideration of SABV in research
 - **U54**: only NIH Center program supporting disease-agnostic research on sex differences (basic, clinical, translational)
 - Career Enhancement Core funds junior faculty and educational opportunities
- R01 – Intersection of sex/gender influences on health and disease (RFA-OD-19-029)
- Sex and gender administrative supplement (NOT-OD-20-049)

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Goal 5



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Methods

Develop methods and leverage data sources to consider sex and gender influences that enhance research for the health of women.

ORWH seeks to improve SABV implementation and evaluation

- Develop tools for large-scale analysis of grant applications
 - Assess consideration of SABV in applications
 - Compare reviewer comments in summary statements
- Engage, recruit, and retain diverse women in clinical studies
 - Disseminate NIH Inclusion Outreach Toolkit
 - <https://orwh.od.nih.gov/toolkit/>
- Enhance clinical research methodology
 - Sex- and age-informed inclusion criteria
 - Sex-stratified randomization, pragmatic trials, adaptive designs



21st Century Cures Act provides a path to progress

Re-affirms commitment to inclusion

- Ensure women and people of ethnic/racial minorities are appropriately represented in clinical research
- Include all age groups in studies
- Strategic plans address women's health & health disparities

Improves sex-specific reporting

- Report % women/men by disease categories
- Applicable Phase III clinical trials must stratify data by sex/gender and race/ethnicity in ClinicalTrials.gov

Enhances NIH coordination of women's health research

- Establishes Task Force on pregnant and lactating women
- Affirms NIH Coordinating Committee for Research on Women's Health

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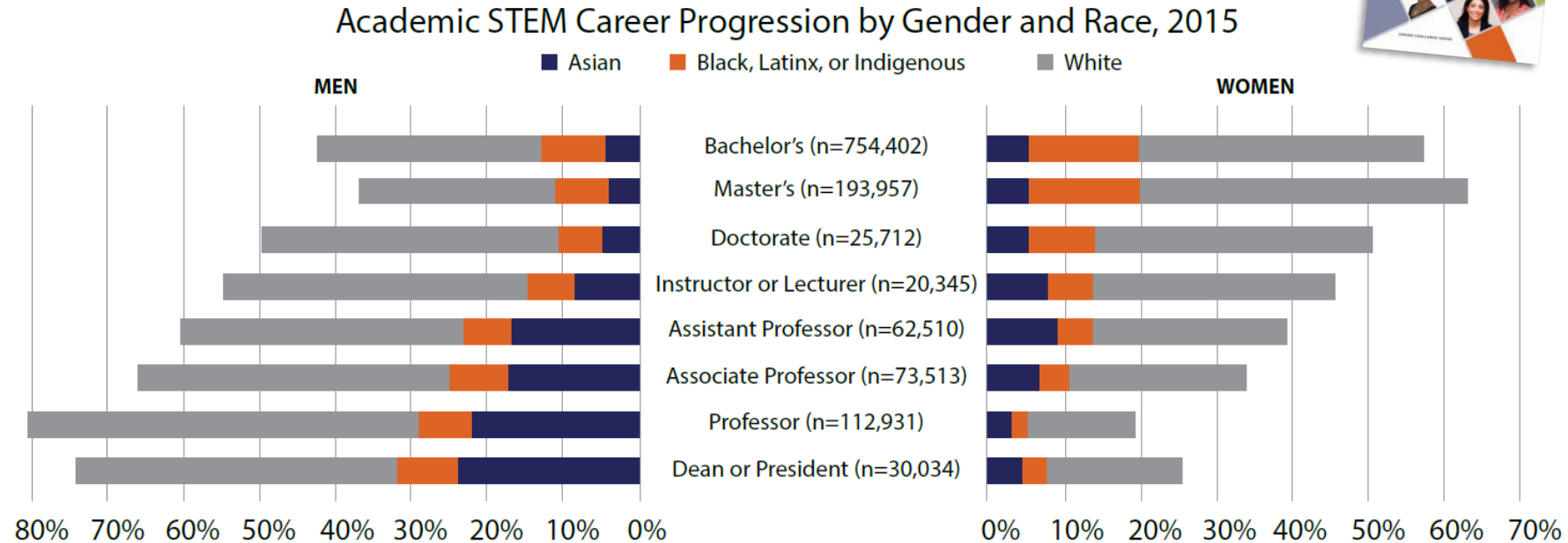
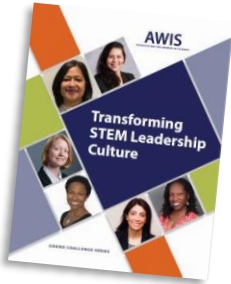
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Strategic Goal 4

Training and Careers

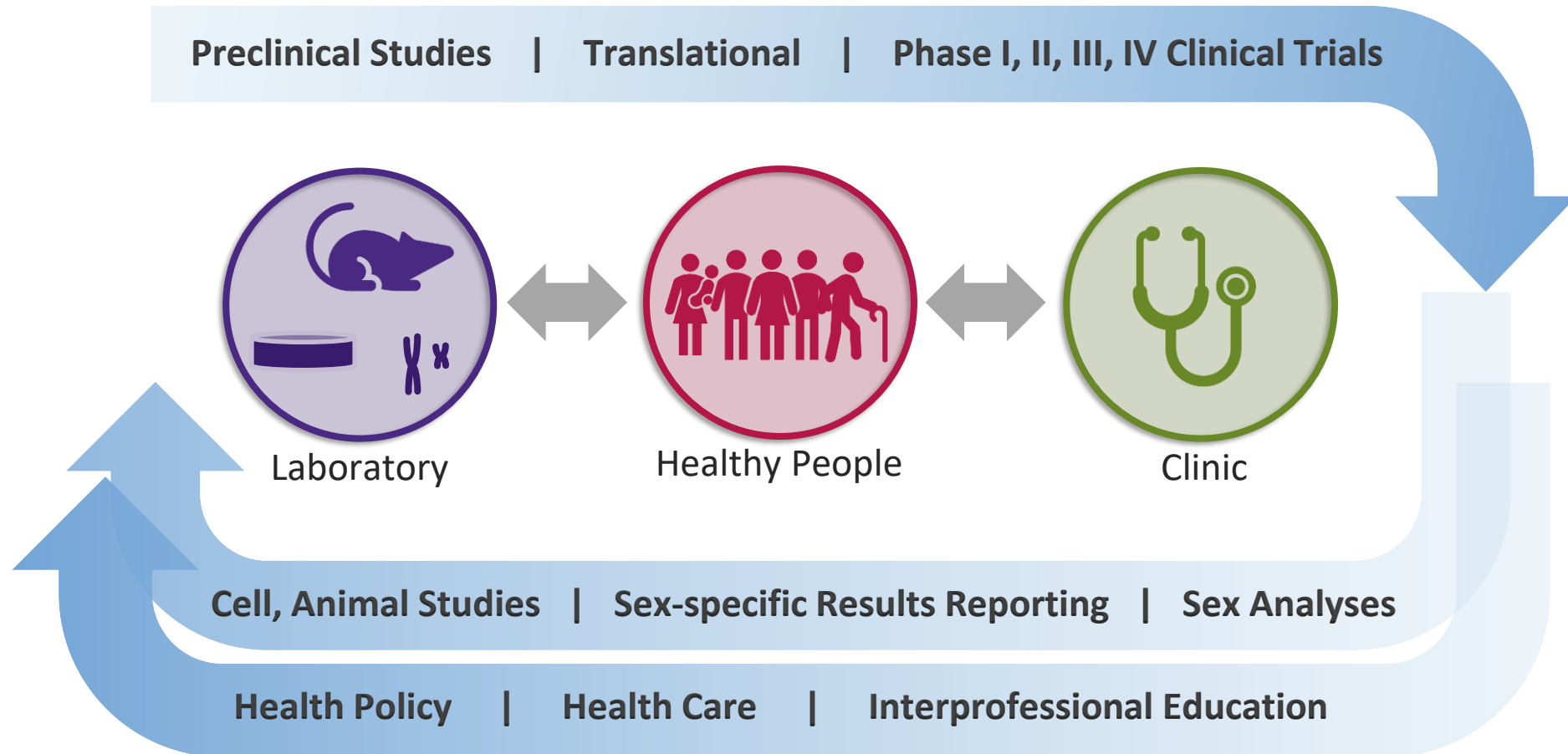
- 4.1 Enhance knowledge of sex differences
- 4.2 Train new scientists in women's health areas
- 4.3 Support women in research careers
- 4.4 Promote practices to retain & advance women scientists
- 4.5 Disseminate research on steps to overcome barriers

ORWH is committed to a diverse workforce to advance the health of women



Metcalf & Russell. 2019. Original analysis of 2015 NSF survey of doctorate recipient and IPEDS data.
https://www.awis.org/wp-content/uploads/2019-Leadership-Report_FINAL_WEB.pdf

Integrating sex/gender across the research continuum to inform and improve the health of women





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In Focus Quarterly bit.ly/ORWHInFocus