

## Women's Representation in Cardiovascular Clinical Trials

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### INTRODUCTION

- Cardiovascular disease is the leading cause of death in women, however, women are consistently under-represented in clinical trials participation [1].
- A large study conducted by Jin et al. (2020) who analysed 740 trials found women's overall participation rate of 38%, ACS (26.9%); heart failure (28.6%); Hypertension (42.4%) [2]. These results are consistent with various studies showing similar rates of participation [1,3,4].
- Disproportionate gender can have a negative impact on generalizability and translation of pharmaceutical trial results to the global population [3].
- The Australian Commission on Safety and Quality in Healthcare's National Clinical Trials Governance Framework (NCTGF) lists patient's sex within the minimum dataset, however it is not yet listed as a mandatory for collection [5].

### SETTING

- The Cardiology Research Unit (CRU) has been operational since 2000
- The CRU has conducted approximately 200, large scale global pharmaceutical trials over the past 20 years.
- There can be up to 300 participants per year from the Barwon South West region of Victoria enrolled in a clinical trial at any one time.
- Participants are mostly recruited from inpatient and outpatient lists from the Cardiology Department at University Hospital Geelong who service the Barwon South West Region.

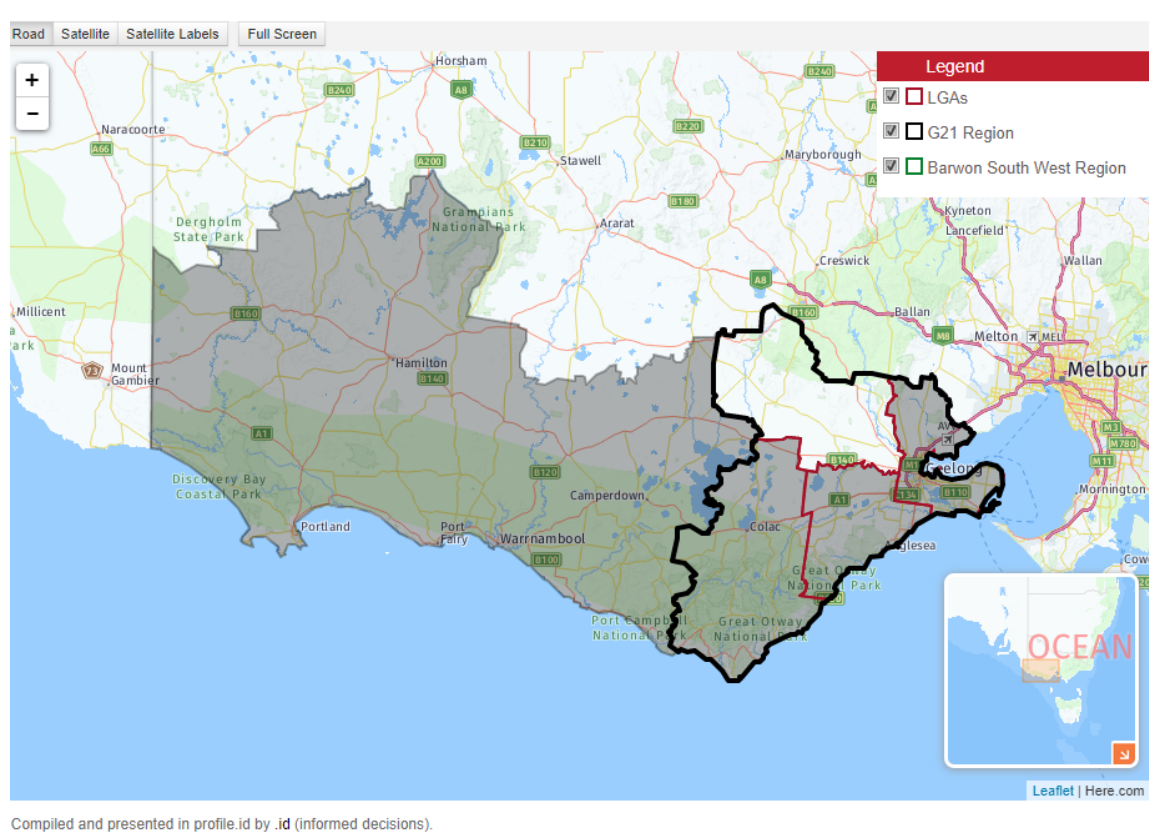


Figure 1: Map of the Barwon South West Region. Population approximately 450,000 people, distance covering 32,700 square km. Of those people aged between 35 and older 52.5% are women. [6]

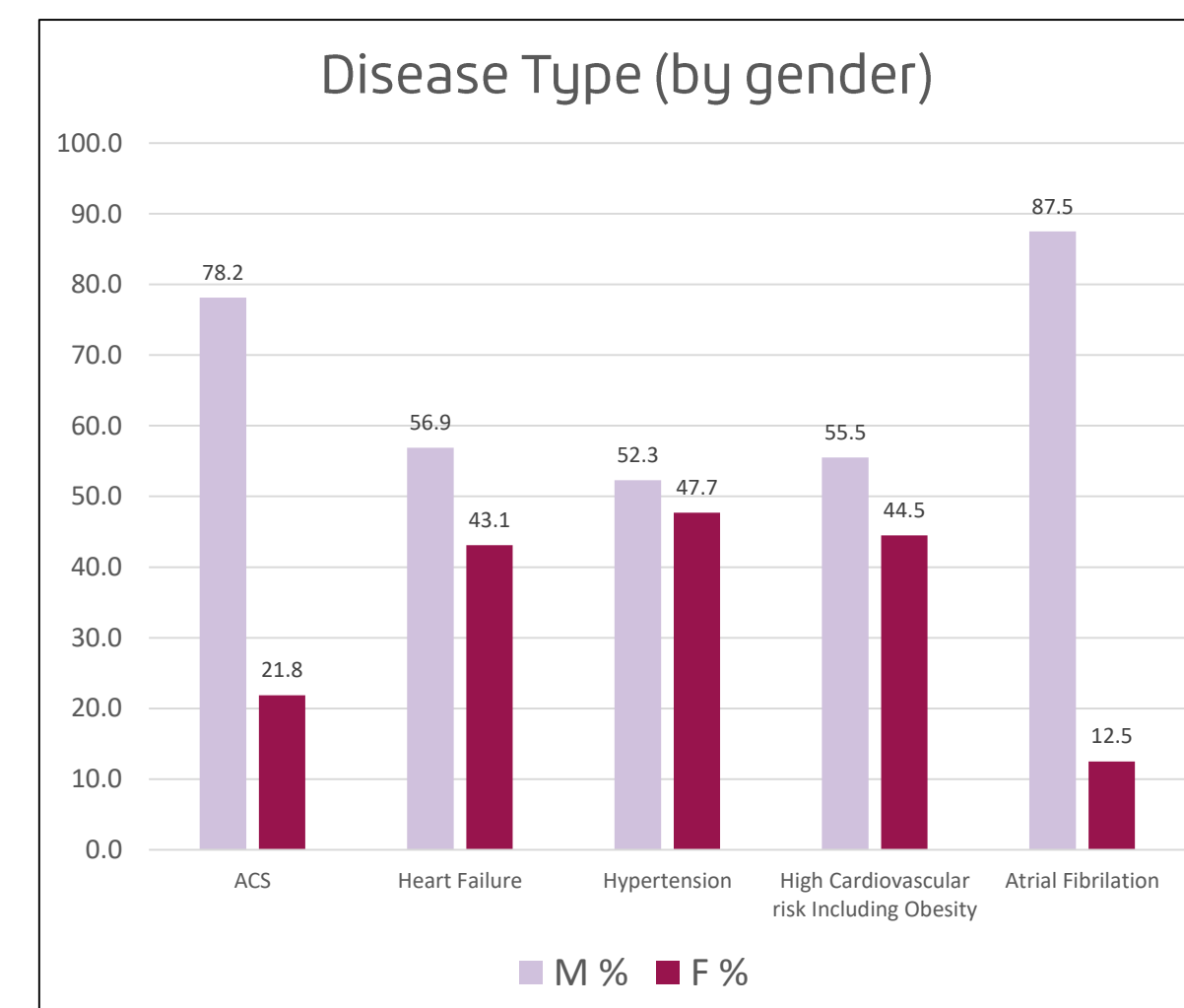
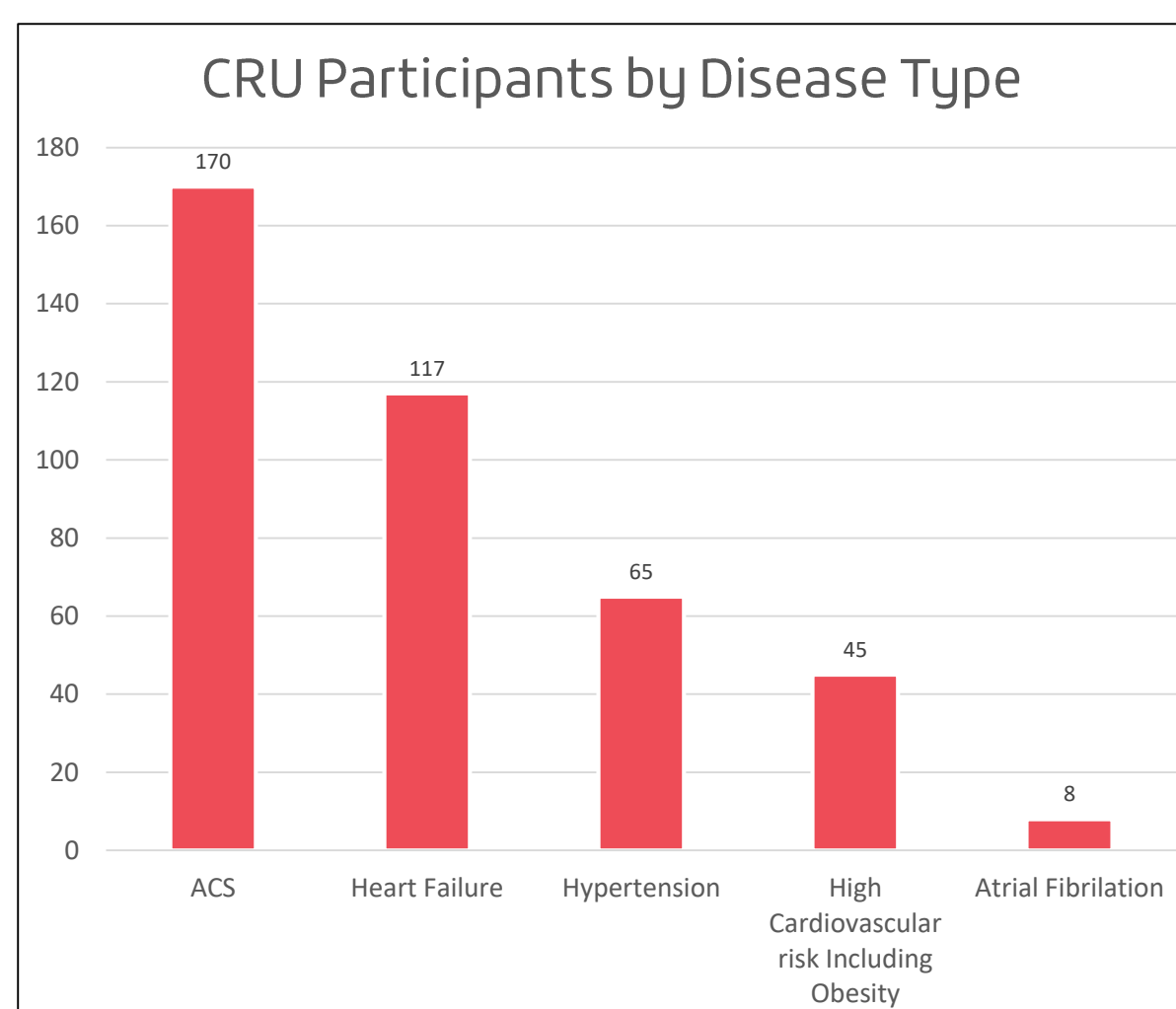
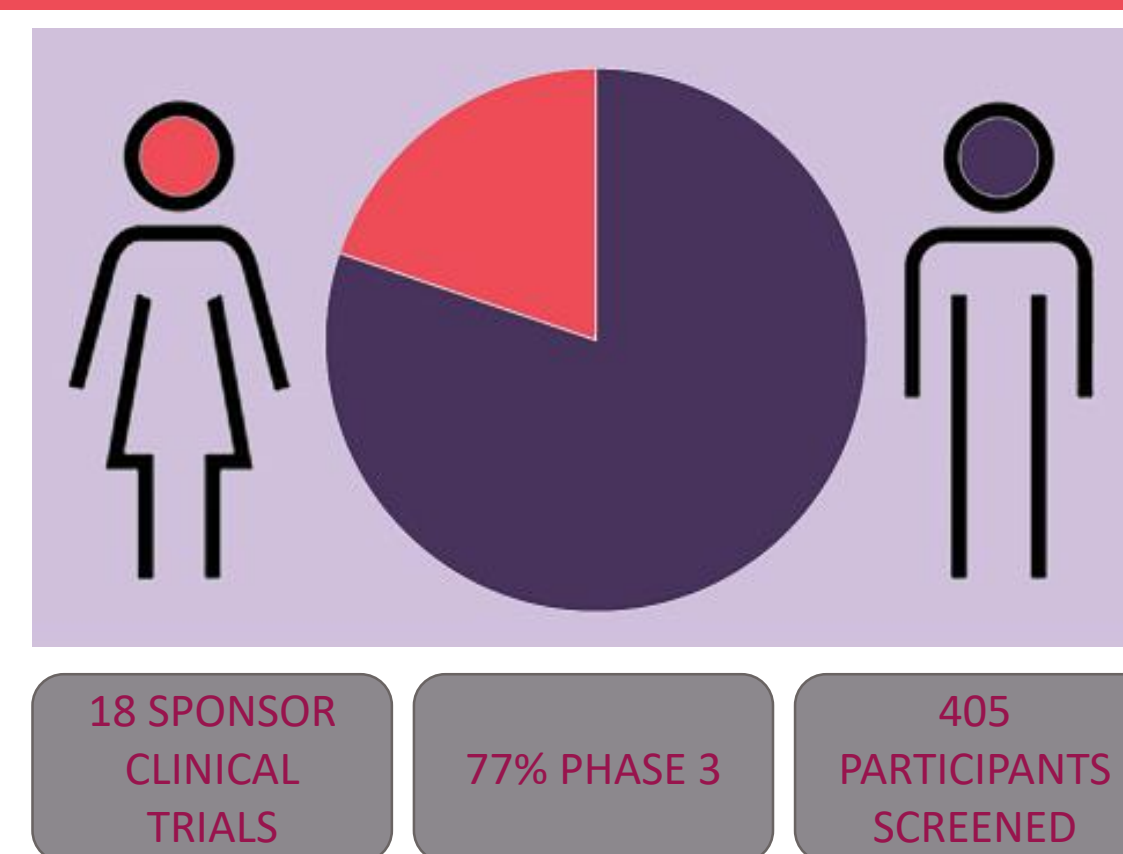
### METHOD

Capture gender metrics of 18 sponsor driven clinical trials between 1 January 2018 to 30 September 2023 from the Cardiology Research Unit. Present gender proportions of CRU participants and UHG admissions. Compare CRU participants by gender and disease type.

### RESULTS

	CRU Participants	UHG Admissions
Male	276 (68%)	4765 (65%)
Female	129 (32%)	2546 (35%)

(Top Left) Table 1: Cardiology Research Unit (CRU) participants vs University Hospital Geelong (UHG) admissions by gender.  
 (Top Right) Figure 2: CRU Participants by gender (Male 68%, Female 32%)  
 (Bottom Left) Figure 3: Number of CRU participants by disease type. ACS=Acute Coronary syndrome, Heart Failure; HFpEF, HFrEF; High Cardiovascular risk, no known cardiovascular disease but high risk, including obesity; Atrial Fibrillation; not including Atrial Flutter.  
 (Bottom Right) Figure 4: Proportion of Disease by gender. Pearson chi2 (df=14) = 46.5342, p-value < 0.001



### DISCUSSION

- 32% of Clinical trials at CRU participants are women. (Mean Age; M: 65.5 years v F: 65.8 years).
- The highest proportion of clinical trials participants were recruited under the disease types of Acute Coronary Syndrome (N=170) and Heart Failure (N=117).
- Women are under-represented in cardiac clinical trials at Barwon Health, particularly those screened for ACS; these rates however are consistent with the literature [1,2,3,4].
- Pleasingly, participants screened for heart failure, hypertension and high cardiovascular risk trials have approximately equal opportunity in participating in a sponsor trial at CRU, which appears better than literature findings for those disease types [1,2,3,4].
- The literature suggests women's under-representation can be due to unconscious bias selection from a perception that certain disease types such as ACS have a high prevalence in men [3]; women take fewer risks in decision making [2]; reproductive age can be exclusionary [3]; and women are undertreated for ACS, have missed or delayed diagnosis and less likely to receive guideline recommended preventive therapies [7].
- Although not proven by this limited analysis, admission rates and clinical trial participation rates at CRU were of similar proportions, 35% and 32% respectively, and may impact on participation.

### OBJECTIVES

To determine the proportion of women who participate in clinical trials at the cardiology research unit.

### CONCLUSION

This project provided a limited but valuable review of gender metrics in clinical trials. It is clear that CRU is consistent with the current literature in terms of women's participation in clinical trials, and in some areas superior to the literature by specific disease types, however, there is much to do in terms of improving equity in clinical trials participation.

It is, however, unknown as to why these disparities exist between gender groups. Further research into understanding why there are differences in trial participation is important, this could allow for improved screening processes to include more women.

CRU to remain competitive in their recruitment strategies.

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