

The **August** meeting of the New South Wales Branch will be held on

Tuesday, 25 August 2009

6:00pm for refreshments and 6:30pm for talk at
Zofrea Room, Level 3, C10A, U@MQ, **Macquarie University**

Ian Marschner

Department of Statistics, Macquarie University

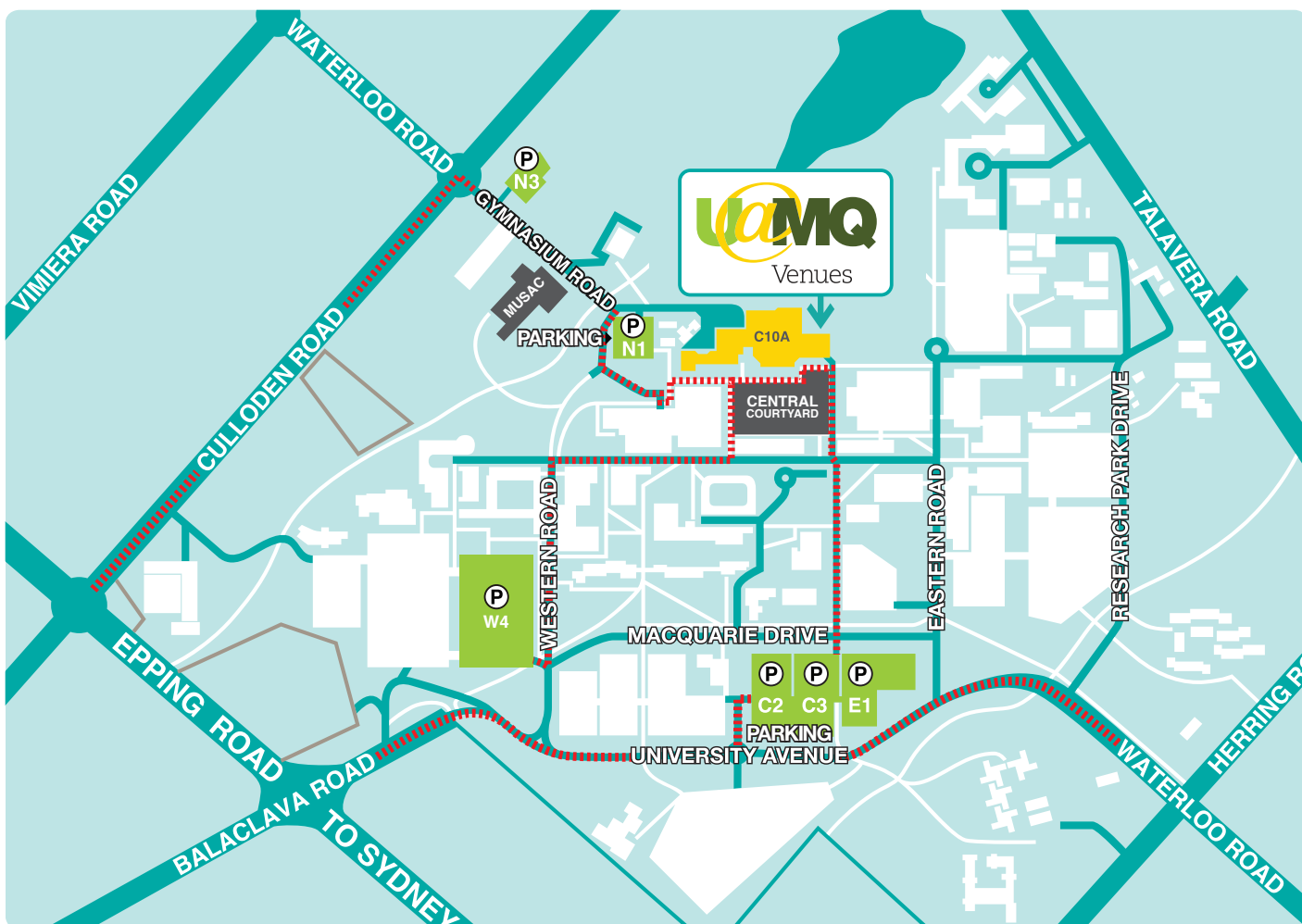
Subgroup Analysis of Randomized Trials: Anticipating Chance Variation During Study Design

Subgroup analysis of a randomized clinical trial can shed light on whether a treatment works differently for different types of individuals. Although it is well understood in theory that subgroup analyses can be misleading due to chance variation, in practice this is often overlooked. I will review a number of real examples of regional subgroup analyses in multinational studies where chance variation is potentially misleading. As a supplement to formal interaction testing, I will propose an approach based on the theory of order statistics that can be used to quantify the expected chance variation during study design. This allows quantification of the expected range of treatment effects and the probability of observing extreme events, such as a harmful subgroup effect from a beneficial treatment. Using these methods it will be shown that wide variation in subgroup treatment effects often occurs due to chance, particularly when the number of subgroups is at least moderate. Even when a treatment is beneficial and the study is well powered, the expected subgroup treatment effects are often likely to include values that favour the control. In light of these results I will advocate that chance variation in key subgroup analyses should be anticipated in study design documentation, particularly for regional effects in multinational studies. This should help to calibrate the expectations of stakeholders and minimize the potential for over-interpretation of subgroup differences.

Ian is Professor of Statistics at Macquarie University. He was formerly Director of Biometrics at Pfizer Australia and prior to that was Associate Professor at Harvard and at Sydney University (NHMRC Clinical Trials Centre).

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