

# THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Wednesday 3rd May 2017 7:15 for 7:45

Amgen Ltd,  
Cambridge Science Park,  
Milton Road,  
Cambridge CB4 0WG

## Innovative statistical approaches for studies in anti-infective drug combination development

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**Abstract:** Combination trials tend to be seen as the pre-dominance of oncology; however, in other therapeutic areas they have many benefits. The treatments for many viral diseases are effective and safe, however, in some there is still a clinical unmet need. Levels of successful vaccination have reduced the need for treatments in some viral diseases, however, where there is a need, current therapies show low efficacy and poor tolerability. Monotherapies are seen to be partially effective, however, it is thought that combinations would provide better efficacy, whilst still maintaining a good safety profile.

The development of combinations in anti-infective drugs rely more on combining two new molecular entities rather than adding onto an existing standard of care. This presents many problems; however, some learning from oncology can help with the development of these combinations.

In this presentation I will show how using an adaptive platform study, combined with Bayesian methods will increase the chances of effective combinations coming to market. Platform trials, where treatment arms are compared to a common control are seen as efficient ways of testing new therapies. The use of Bayesian stopping rules for futility allow for stopping of ineffective arms. The use of borrowing also boosts efficiency. These ideas combined with Phase II/III designs boost efficiency in registering new combination therapies.

**Speaker:** Alun Bedding has worked in the Pharmaceutical Industry for 28 years and has experience in all areas of drug development, from pre-clinical to post registration. Alun currently works as an Associate Director in Roche, leading a team in early clinical development and has worked at many other companies including AstraZeneca, GSK and Eli Lilly. Alun's specialisms are model based dose finding and adaptive clinical trials. He is a member of the DIA Adaptive Designs Scientific Working Group and is also a panel member for the MRC Development Pathway Funding Scheme.

**Directions:** Head north on Milton Road. Two traffic lights before the A14 turn left into the Science Park (clearly signposted). Turn left at the roundabout. The meeting takes place at Amgen in the restaurant in building 214 (the ground floor of the middle building on the attached map which is also at <http://imaging.mrc-cbu.cam.ac.uk/statswiki/csdg/amgen>). Parking is available on site. There will be no admittance after 7-45pm. Arrivals after 7-45pm can gain admittance by contacting the secretary on 07761769436. **If anyone would like complementary transport to the talk venue from Central Cambridge please inform the secretary in advance of the meeting.**

### Provisional Next Meetings:

10th October – Zoubin Ghahramani (Engineering). 20th November – Adam Kashlak (Statistical Laboratory).

5th February 2018 – Anthony Edwards (Gonville & Caius) on 'Cambridge Statistics from Venn to Fisher and Beyond'.

**Supper:** Some members eat regularly in the University Centre before each meeting at 5-45pm. Feel free to join them.

**Subscriptions:** of 1 pound are now due for attending the 2016-2017 session.

**Secretary:** Peter Watson, MRC Cognition and Brain Sciences Unit, 15 Chaucer Road, Cambridge CB2 7EF; telephone 01223 355294 Extension 801; E-mail [peter.watson@mrc-cbu.cam.ac.uk](mailto:peter.watson@mrc-cbu.cam.ac.uk)

**Slides and .mp3 files of old talks:** <http://www.mrc-cbu.cam.ac.uk/people/peter.watson/csdg.html>