

THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Thursday 9th May 2002 7:15 for 7:45

Honor Fell Room,
Strangeways Research Laboratory,
Worts Causeway, Cambridge

Eleven Years of Statistics and Statistical Issues in the Pharmaceutical Industry

Krys Kelly

Formerly of Amgen Ltd,
Cambridge

Abstract: I was taught by my very old fashioned tutor that the three important principles of biological experimentation are replication, randomisation and restraint, the latter meaning control. I will deal with control in its most general sense, focussing on issues for Randomised Controlled Clinical Trials using examples from my 7 years in academia and 11 in the pharmaceutical industry. This will include control groups, stratification, eligibility criteria and regulation including audit. I will touch on the implications of the Declaration of Helsinki as amended in 2000 and the International Conference on Harmonisation (ICH) guidelines "E9" on Statistical Principles for Clinical Trials and "E10" on Choice of Control Group.

Speaker: During her PhD and following 6 years in Birmingham, Krys developed statistical methodology for analysing human variation, with applications in disease and behaviour. She then spent 7 years with the newly formed West Midlands CRC Clinical Trials Unit as Head of Statistics and IT, helping to develop and manage the Unit as well as contributing to clinical trial methodology. In 1990, she joined Amgen to set up the Statistics Function in Europe, becoming Director of Statistics and Clinical Data Management. As well as contributing to the design and implementation of global clinical programmes leading to product registrations, she led a group of up to a hundred statisticians and data managers.

Directions: Head away from Cambridge city centre along the Hills Road. About 200 yards after the hospital roundabout a road (signposted 'Fulbourn 3') forks off to the left – this is Wort's Causeway. Strangeways Research Laboratory is the first building on the right on Wort's Causeway. There is car parking both at the front and the rear of the building. Access to the building may be difficult after 7:45.

Provisional Next Meeting:

7th October – Ian MacPherson (PRISM) on 'Exploiting Biological Potential'.

Supper: Some members eat before a talk at the University Centre meeting in the downstairs bar at 6pm. All welcome !

Subscriptions: of 4 pounds per member are now due for the 2001-2002 session. Cheques should be made payable to Peter Watson and may be posted to the secretary at the address below.

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