#### THE CAMBRIDGE STATISTICS DISCUSSION GROUP

### Tuesday 11th October 2016 7:15 for 7:45

Large Lecture Theatre, MRC Cognition and Brain Sciences Unit, Chaucer Road, Cambridge, CB2 7EF

# Driving the Robustness of Preclinical Research within the Pharmaceutical Industry Katrina Gore, Independent Statistical Consultant

Abstract: In the past few years it has been hard to pick up a copy of Nature, Science or many preclinical biomedical research journals without seeing an article on the issue of non-reproducible research. They all acknowledge that research is plagued by findings that are not reliable and just cannot be reproduced. The pharmaceutical industry is not immune to these issues. Replication of published research findings is a key component of drug target identification and provides confidence to progress internal drug projects into the discovery pipeline. We also use data from internal assays to assess the biological and pharmacokinetic activity, selectivity and safety of novel compounds and make decisions which impact their progression towards clinical development. Many pharmaceutical companies have statisticians engaging with research scientists however the ratio of statisticians to scientists is typically low. This talk will describe the role of a preclinical statistician, outline the key challenges they face and focus on how Pfizer is implementing the Assay Capability Tool. The ACT was created by Research Statistics within Pfizer to guide the development of drug discovery assays and to address issues of robustness and reproducibility in research. It promotes easy to follow but absolutely essential experimental design strategies and represents the distilled experience of the provision of over three decades of statistical support to laboratory scientists.

**Speaker:** Katrina has over 20 years of experience as a statistician in the Pharmaceutical Industry. In 1995 she joined Pfizer in sandwich, Kent as a pre-clinical statistician to anirmal health and human cardiovascular teams supporting scientists across aspects of drug discovery from early target identification to late-stage preclinical in vivo experiments, across a wide variety of therapeutic areas. In 2011 she moved to Pfizer Neusentis in Cambridge, providing statistical leadership to early phase clinical programs for pain, regenerative medicine and neuroscience research projects and also coordinated pre-clinical support to scientists. Katrina co-developed Pfizer's Assay Capability Tool, improving the scientific rigour of experiments and drug development decision making. Her team were join winners of the PSI/RSS Statistical Excellence in the Pharmaceutical Industry award in 2015. This summer she left Pfizer to become an independent statistical consultant. **Annual General Meeting:** Katrina's talk will be preceded by a brief AGM.

**Directions** Chaucer Road is off Trumpington Road – if you are heading away from the city centre it is the first right after the junction with Brooklands Avenue. Number 15 is at the end on the left and is a large Victorian House with a more modern extension to its right. The entrance is in the porch located in the middle of the older section on the left as you come in and is accessed by ascending a few steps from the car park. Cars may be parked there. The outside door will be locked at 7:45.

Arrivals after 7:45pm can gain admittance by contacting the secretary on 07761769436. A map showing the location of the unit is at http://www.mrc-cbu.cam.ac.uk/contact-us.

#### **Provisional Next Meetings:**

21st November – Nick Galwey (GlaxoSmithKline) on 'Use of historical information to supplement a future study: opportunity and difficulty'. 2nd February 2017 – David Excell (Featurespace).

7th March – Patricia Fara (Clare College) on 'A lab of one's own: science & suffrage in the First World War'.

3rd April - Daniel Gaffney (Sanger). 3rd May - Alun Bedding (AstraZeneca).

**Supper:** Some members eat before a talk at the University Centre meeting in the Granta Lounge at **5-45pm**. All welcome! **Secretary:** Peter Watson, MRC Cognition and Brain Sciences Unit, 15 Chaucer Road, Cambridge CB2 7EF; telephone 01223 355294 Extension 801; E-mail <a href="mailto:peter.watson@mrc-cbu.cam.ac.uk">peter.watson@mrc-cbu.cam.ac.uk</a>

For security purposes could you please let Peter Watson know if you intend attending the talk. Slides and .mp3 files of old talks: http://www.mrc-cbu.cam.ac.uk/people/peter.watson/csdg.html TURN OVER for the Annual General Meeting agenda

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## **Annual General Meeting**

The annual general meeting will be followed immediately by Katrina's talk 'Driving the Robustness of Preclinical Research within the Pharmaceutical Industry'.

#### Agenda:

- Approval of Minutes of previous A.G.M. (http://imaging.mrc-cbu.cam.ac.uk/statswiki/csdg/newtalks)
- **1.** Treasurer's Report.
- **2.** Secretary's Report.
- **3.** Election of Chairman, Secretary, Treasurer, plus 3 other members of the Committee.
- **4.** Any Other Business.

#### **Rules for Election:**

- 1. FRANCISE: All paid-up members may vote or stand for office.
- 2. NOMINATIONS: The offices to be filled are Chairman, Secretary and Treasurer and three other members of the Committee.

An outgoing Chairman will be a member of the Committee ex officio. At the end of each year the entire Committee will stand down, but may stand again for the same office as they are leaving without nomination. To be elected to a different office a candidate must be nominated by one person from the paid-up membership, not including himself. Nominations do not require a seconder to be valid, but do require the consent of the nominee. One person can be nominated for more than one office, but hold only one. If a person is elected to a higher office (according to the ordering given below) he or she automatically ceases to be a candidate for a lower office. A candidate for the post of Chairman, Secretary, Treasurer is automatically a candidate for the Committee if he or she fails to gain election to one of these three posts.

TURN OVER for directions to the Cognition and Brain Sciences Unit and abstract of Katrina's talk