THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Tuesday 8th October 2024 7:15 for 7:45

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

A conservative approach to leveraging external evidence for effective clinical trial design

Fabio Rigat
AstraZeneca

Abstract: Prior probabilities of clinical hypotheses are not systematically used for clinical trial design yet, due to a concern that poor priors may lead to poor decisions. To address this concern, a conservative approach to Bayesian trial design is illustrated here, requiring that the operational characteristics of the primary trial outcome are stronger than the prior. This approach is complementary to current Bayesian design methods, in that it insures against prior-data conflict by defining a sample size commensurate to a discrete design prior. This approach is ethical, in that it requires designs appropriate to achieving pre-specified levels of clinical equipoise imbalance. Practical examples are discussed, illustrating design of trials with binary or time to event endpoints. Moderate increases in phase II study sample size are shown to deliver strong levels of overall evidence for go/no-go clinical development decisions. Levels of negative evidence provided by group sequential confirmatory designs are found negligible, highlighting the importance of complementing efficacy boundaries with non-binding futility criteria.

Speaker: Fabio leads gastro-intestinal oncology biometrics at AstraZeneca, to advance our pipeline on behalf of cancer patients. His work here focuses on strategy and execution of late phase clinical trials against oesophageal, gastric, liver, biliary tract, pancreatic and colorectal cancers. He also works in statistical innovation, to improve the effectiveness and impact of statistical methods used for experimental design, data analysis and decision making. Prior to this he worked in preclinical and clinical biostatistics developing vaccines, immuno-inflammation and oncology medicines. Before joining the pharmaceutical industry, he worked in excellent academic institutions learning, teaching and developing statistical models and computational methods for data analysis in oncology, cardiovascular disease and neuroscience.

Annual General Meeting: Fabio's talk will be preceded by a brief Annual General Meeting.

Directions (From Central Cambridge) 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. Note due to building work please enter and leave car park via the 'OUT' entrance (the second of the two entrances on the left as you go down Chaucer Road). 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:
4th November - Mihaela van der Schaar (Cambridge Centre for AI in Medicine).
27th November – Peter Treasure (Peter Treasure Statistical Services Ltd).
3rd February 2025 – Lara Mani (formerly Centre for the Study of Existential Risk).
3rd March – James Grime (Institute of Continuing Education) on 'Alan Turing and the Enigma Machine'.
10th April – Roger Sewell on 'Predicting recurrence of prostate cancer: a Bayesian approach'.
Supper: Some members eat regularly in Wetherspoons (St Andrew's Street) before each meeting **at 5-45pm**.All welcome !

Subscriptions: of 1 pound are now due for attending the 2024-2025 session.
Secretary: Peter Watson, MRC Cognition and Brain Sciences Unit, 15 Chaucer Road, Cambridge CB2 7EF;
telephone 01223 769479; E-mail 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
SEE NEXT PAGE for the Annual General Meeting agenda

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Annual General Meeting

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The annual general meeting will be followed immediately by Fabio's talk 'A conservative approach to leveraging external evidence for effective clinical trial design'.

Agenda:

0.   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 Fabio's talk