Statistical Consultancy

Manchester RSS
March 2014
PHASTAR

- 33 statisticians
  - PhD/MSc
  - SAS
  - 8 years experience

- 12 programmers
  - MSc/BSc
  - CDISC expertise
  - Up to 15 years

Our Consultants...

- Technical skills
- Programming
- Communication
- Influential

- Operations Director
- Operations Manager
- Business Development/Recruitment
OUR SERVICES

- Reporting Data
- Phases 1 to 4; Pre-clinical
- Clinical Trials
- Integrating data
- CDISC conversion
- IDMC
- Observational Data
- Meta-Analyses
- Safety Reviews
- Observational Data

- Statistical Consulting
- Trial Design
  - Optimal designs
  - Sample size calculations
  - Bayesian adaptive designs
- Modelling & Simulation
- Submission Support
- Publication Support
  - Experience working with clinical and commercial teams
- Health Outcomes
- Health Economics
How we spend our time

- Trial analysis
- Consulting
- Programming
Case study: Optimising study design

- Respiratory study with a new response outcome
- Measured weekly for 1 year
- “What’s the best way to analyse these data”? 
- There was some data measured in other studies – monthly measurements
Case study: Optimising study design

- Developed a model for the response over time

![Graph showing an exponential curve with a parameter for "half life" and a linear component with a gradient to allow rotation. The graph also includes a random subject effect.]

Also includes random subject effect.
Case study: Optimising study design

- Fit this model to existing data:

- Simulate weekly data using this model
Case study: Optimising study design

• Compare different analysis strategies:
  – Calculate proportion of successful weeks per patient
    • Parametric and non-parametric analysis of this outcome
    • Absolute and relative differences
  – GEE modelling
  – Survival analyses

• We recommended a repeated measures logistic regression using GEE
Research: Sample size assumptions

- Prior hypothesis that drug development teams are not good at making assumptions needed for sample size calculations
- Prof Tony O’Hagan’s talk at PSI on elicitation to build up prior belief
- Conducted a literature review to compare planned effect sizes with observed effect sizes
- Utilise clintrials.gov, medline, company registries
Research: Sample size assumptions

Median = 114%
CRO vs Pharma

– External stakeholders vs internal stakeholders
– Communication is important
  • Verbal and written
  • Essential to be able to communicate statistical ideas to other statisticians and clinicians
  • Taking a problem and formulating it into a solvable problem
  • To negotiate when there are differences of opinion
– More transparent business process
– Estimates of required resources
– Deadline focussed
– Working environment
CRO vs Pharma

– Pharma industry in the UK may be contracting
– CRO industry expanding
  • Estimated expansion 11.4% per year until 2017
– We have had an average growth of 49% in the last 6 years
– Opened offices in Kent and are opening in Alderly Park in the BioHud at the AstraZeneca site.
– Planned expansions in Switzerland and the US