Proposed Best Practice for Statisticians in the Reporting and Publication of Pharmaceutical Industry Sponsored Clinical Trials

James Matcham, Steven Julious, Stephen Pyke,
Michael O'Kelly, Susan Todd, Jorgen Seldrup,
John Davies and Simon Day

Background

- This is a proposal for industry statisticians
- To start a general debate amongst pharmaceutical statisticians, and others
- These are the views of the authors
- We highlight the importance of the trial statistician as an author

Eight Best Practice Proposals

- Author responsibilities
- Publication timing
- Conflicts of interest
- Freedom to act
- Full author access to data
- Trial registration
- Trial originality
- Independent review

Author Responsibilities

The statistical author should be responsible for the statistical aspects of the paper

- The trial statistician should be an author
- Appropriately identify protocol methods and justify any departures
- Appropriately reflect any DMC (and support) statistician and their roles

Publication Timing

Protocols should be published in a publicly available and timely manner

- Trial statistician ensures that published protocol appropriately identifies; objectives, endpoints, design, sample size and methods of analysis
- Allows reviewers and editors to confirm pre-definition

Conflicts of Interest

Financial and other conflicts of interests should be disclosed

- Clear statement of who sponsored the trial
- Declare employee or contractor status
- Declare any financial interests
  (stock ownership, grants etc..)

Freedom to Act

The authors should have freedom to act

- Trial statisticians should have no impediment to appropriately presenting the results
- Trial statisticians are taking professional responsibility for accuracy of results and the true and fair presentation of the results

Full Author Access to Data

All authors should have full access to trial data

- Trial statisticians should ensure that the data and results are presented to each author
- Ensure that authors can access and understand the results
- Facilitate communication between all authors to address any questions

Trial Registration

The results should be publicly registered

- Results should be published through
  - publicly accessed forums (eg public websites)
  - peer reviewed journals
- All publications should be linked to the published protocol
- The trial statistician should ensure that available results are understandable to subsequent users

Trial Originality

The results should be original

- Results should be published in a timely manner
- Highlight any results presented previously at congresses or other publications

Independent Review

Any independent statistical review should be highlighted

- The publication should state any independent review at the design or analysis stage made by any non-sponsor staff
- Could include independent experts or regulators

Future Possibilities?

- Some possible future developments could include
  - publishing individual patient data in a publicly available manner
  - regulatory bodies publishing detailed reviews of trials in drug applications
  - electronic access to CVs of each author
  - and others

Summary

- All authors have responsibilities, the trial statistician has particular responsibilities
- These proposals should act as the beginning of a discussion
- These may be revisited and updated in the future