Towards Structured Use of Bayesian Sequential Monitoring in Clinical Trials

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Abstract

The text of your abstract. 200 or fewer words.

Keywords: 3 to 6 keywords, that do not appear in the title

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1 Introduction

Things to discuss:

- 21st Century Cures Act (MATT)
- PDUFA VI reauthorization (MATT)
- Expansive work already done on sequential monitoring (EVAN – draft on 6/21)
- Our majors contribution (EVAN – as early as possible in introduction without having the flow appear weird – draft on 6/21)
- Outline for the remaining section of the paper (EVAN – draft on 6/21)

2 Methods

As you introduce ideas that come from or extend other ideas in the literature, cite the relevant literature.

2.1 Monitoring versus Estimation Priors (EVAN – draft on 6/21)

- Define generally in terms of $\boldsymbol{\theta} = (\gamma, \boldsymbol{\psi})$ where γ is a parameter of interest and $\boldsymbol{\psi}$ is a nuisance parameter (possible vector valued).
- Define *Monitoring* Priors and *Inference* Priors.
- Make connection between Inference priors and two-part mixture prior and BMA.
- Define *Skeptical* and *Enthusiastic* monitoring priors and how each would be used.

- I would have a generic graphic to illustrate the types of priors and the mixture.

2.2 Futility Monitoring Using Probability of Success (EVAN – draft on 6/21)

- Futility monitoring using POS is about stopping early when their is a high likelihood of a study being inconclusive at the end of the study.
- Since the final analysis uses the *Inference* prior, POS should be based on the inference prior.
- Develop the framework for POS and show how it is a weighted average POS based on the skeptical and enthusiastic priors.

3 Examples – (EVAN)

3.1 Single-Arm Oncology Proof-of-Activity Trial w/ Binary Endpoint

3.2 Parallel Two-Group Superiority Trial /w Continuous Binary Endpoint

3.3 Three-Arm, Placebo Controlled Non-Inferiority Trial w/ Continuous Endpoint

4 Discussion – (MATT/EVAN)

SUPPLEMENTARY MATERIAL

5 BibTeX

References