

DEPARTMENT OF BIOSTATISTICS & DATA SCIENCE

Estimating the Best Commute: Trial Design and Execution

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FACTS Working Group
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Introduction

- Reducing amount of time spent driving from home to work can help maximize productivity in the work place.
- Compare designs to determine the optimal driving route from Dr. Gajewski's home to his work place at KUMC.
- Three route option: Plaza (control), Rainbow, Stateline.

Groups

1. DIAS
2. The StarFish
3. Lauren&Elena
4. JZ
5. Byron

**All designs considered Independent dose model.*

Design Proposed by DIAS group

- Deterministic accrual.
- Final endpoint = 0.01 weeks.
- No dropout rate.
- Externally predefined accrual file.
- Burn-in allocation ratio: 2:1:1 then RAR.
- 25% allocation to the control.
- Block size = 4
- Interims 3 at 8,16,24 and final analysis at 33.

Design Proposed by Starfish group

- Continuous recruitment.
- Weeks means days.
- Dropout rate 0.05.
- Burn-in allocation ratio 2:2:2.
- Interims 2 at 12, 24 and final analysis at 33.
- Block size = 6
- Optimistic prior.

Design Proposed by Lauren & Elena

- Arm dropping.
- One interim at 15 and final analysis at 33.
- Only futility criteria.
- Optimistic prior.

Fixed Design Proposed by JZ

- Continuous recruiting.
- Dropout rate 0.1.
- 1:1:1 fixed allocation.
- No interims, final analysis at 33.
- Delta is about -1 minute.
- Zero type I error rate.
- Changed the continuous to deterministic.
- Use externally predefined accrual file from the 'DIAS' group.
- Changed dropout rate to 0.

Two RAR Designs Proposed by Dr. Gajewski

1. Fixed control allocation throughout the trial:

- Deterministic accrual.
- Final endpoint 0.01 weeks.
- No dropout rate.
- Burn-in allocation ratio 4:3:3 then RAR.
- 40% allocation to the control.
- Block size = 10
- Interims 5 at 10,15,20,25,30 and final analysis at 33.

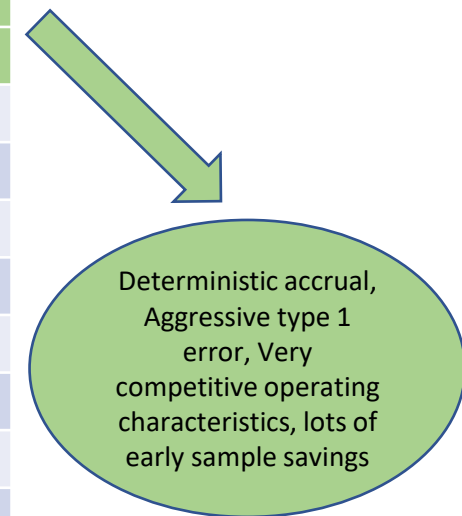
2. No fixed control: Everything is same except no fixed allocation for control.

Initial Designs & Results

Team	Design Type	Time to final endpoint	Hypothesis	Mean subjects	Type 1 error rate/ Power
DIAS	Adaptive, RAR, deterministic accrual	0.01	Null	23.55	0.024
			Expected	23.59	0.980
			Best	25.11	0.944
TheStarFish	Adaptive, continuous	1 ("weeks" means "days")	Null	29.48	0.024
			Expected	32.89	0.949
			Best	31.93	0.897
Lauren&Elena	Adaptive, continuous, arm dropping	1 ("weeks" means "days")	Null	30.13	0.020
			Expected	33	0.987
			Best	32.98	0.937
JZ	Fixed, deterministic	0.15	Null	33	0.015
			Expected	33	0.979
			Best	33	0.926
Byron	RAR, deterministic (fixed allocation to control)	0.01	Null	25.55	0.020
			Expected	22.53	0.978
			Best	24.11	0.935
Byron	RAR, deterministic (No fixed control arm)	0.01	Null	25.67	0.026
			Expected	24.34	0.902
			Best	25.39	0.886

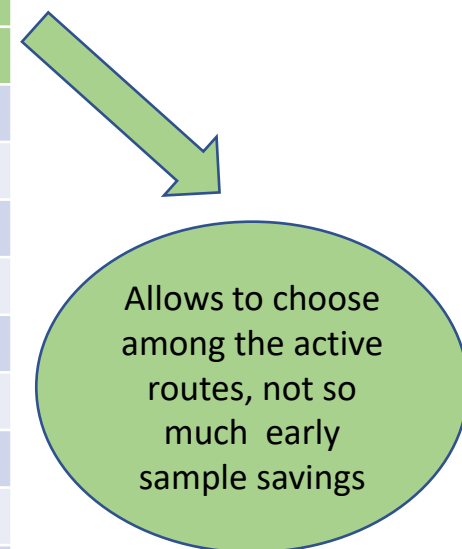
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Gives better driving experience, not so much early sample savings

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Competitive power,
No early sample savings

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Competitive operating characteristics but higher interims.

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Good operating characteristics, higher interims

Final Design Selection

TEAM DIAS

Final Design: Design Proposed by Team DIAS

- Best operating statistics.
- Less interim analysis.
- The power of the one best scenario is 94.4%, which is superior to any other design's power.
- The expected number of drives under all scenarios are the smallest (23.546, 23.587, and 25.113), which reduces the trial duration.

Milestones/Products

- 1) Design (FACTS) (co-I: Elena)
- 2) Protocol (co-I: Geeth/Kate) – Nov 10th
- 3) Statistical Analysis Plan (Geeth/Kate)
- 4) Data Capturing (RedCAP and a Shiny App for Randomization) (Sreejata/Fred)
- 5) Analysis (Kaustubh/JZ)
- 6) Paper(PI)

Milestones/Products

- 1) Oct 27th → Discuss questions related to the project
 - Dropouts, blinding, user access of REDCap and Shiny App, subject matter expert, human subject form
- 2) Nov 10th → Kate & Geeth will be sending the protocol/ SAP for review via email
- 3) Nov 13th → Submit protocol and human subjects form to IRB
- 4) Elena will be discussing with Dr. Gajewski about re-scheduling meeting to Nov 17th
- 5) Nov 17th → Fred & Sreejata will be finalizing the data base/ Randomization/Shiny app



Thank You!