Biostatistics and Clinical Informatics Shared Resource Facility: Biostatistics

Mount Sinai — The Tisch Cancer Institute

"Providing state-of-the-art clinical trial design, statistical analytics, and training "

BACKGROUND

- The multidisciplinary nature of cancer research studies frequently raises novel design and analytic challenges.
- Biostatisticians play a key role in these studies in a variety of ways:
  - designing studies efficiently to address pertinent hypotheses
  - guiding the creation of appropriate databases
  - ensuring the feasibility of the planned analyses
  - analyzing study data; providing proper interpretation of results
  - developing novel design and analytic methods.

SERVICES

Services Supported by NCI-CCSG (Free of Charge)

- Grant development and review
- Interventional - Investigator Initiated Trial (I-IIT) protocol development and review
- Statistical analysis of data directly related to an I-IIT
- Assistance with journal clubs and paper review
- Teaching short courses in design and analysis methodology
- Mentoring for Young Investigator and K awards

Services Supported by Grants or Contracts

- **Statistical analysis of data directly related to grant or a Non-Interventional IIT project**
- **Assistance with manuscript writing and review**
- **Assistance with research conferences**
- **Assistance with identification of research gaps to initiate new research topics**

MEMBERS/EXPERTISE

Erin Moshier, MS
Managing Director
Group-based trajectory modeling

Marcio Diniz, PhD
Co-Director
Bayesian clinical trial design

John Mandeli, PhD
Associate Professor
Pilot / Feasibility study design

Madhu Mazumdar, PhD
Co-Director
Pragmatic clinical trial design

Deukwoo Kwon, PhD
AD, AMC, Associate Professor
Clinical trial design with external control

Himanshu Joshi, PhD
Assistant Professor
Predictive modeling and cancer genomics

Seungjun Ahn, PhD
Assistant Professor
Differential network analysis for -Omics data

Xiaoyu Song, PhD
Associate Professor
Integrative data analysis for multi-omics data

Francesca Petralia, PhD
Assistant Professor
Bayesian algorithm development for -Omics data

Lewis Tomalin, PhD
Assistant Professor
Bioinformatics, Computational Biology

Asem Berkalieva, MS
Senior Biostatistician
Group sequential design

Weijia Fu, MS
Biostatistician II
Multi-omics data analysis

Grace Van Hyfte, MS
Biostatistician II
Longitudinal biomarker and time-to-event joint modeling

Mayuri Jain, MS
Biostatistician I
Geographical spatial data analysis

FUNDING MODELS

Grants:
- Biostatistician's salary charged at fixed %FTE (negotiated up front during grant development)
- PhD + MS statisticians recommended for large grants

Fee for Service Contracts:
- Charged at a subsidized hourly rate of $125
- Requiring a minimum of eight hours of work.

Long-term Collaboration Contracts:
- Investigator's departmental funds used to support Biostatistician's salary charged at fixed %FTE
- With matching dollars provided by the NCI-CCSG

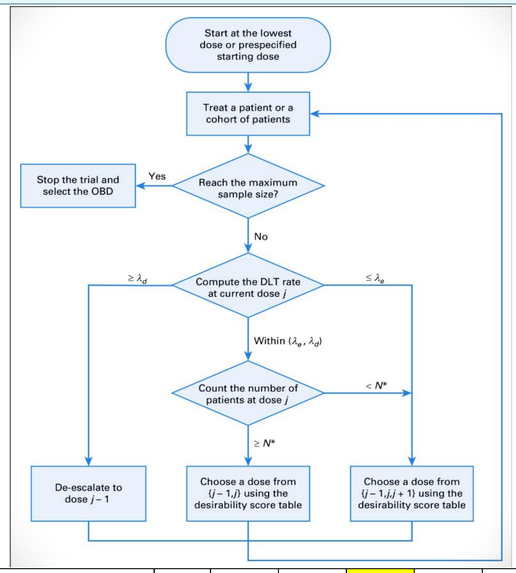
SAMPLE PROJECT

IIT designed with Bayesian Optimal Interval Phase I/II (BOIN12)

Goal:
- **To assess the safety and efficacy of a combination regimen for patients with Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) overlap syndrome**

Why this design is most optimal?
- **Maximum tolerated dose (MTD) may not be the optimal dose for treating patients on novel therapies whose efficacy does not increase with dose escalation.**
- **Identifying the optimal biologic dose (OBD) that optimizes patients' risk-benefit trade-off becomes the target**
- **BOIN12 design is most optimal for finding OBD as it makes the decision of dose escalation and de-escalation by simultaneously taking account of efficacy and toxicity and adaptively allocating patients to the dose that optimizes the toxicity-efficacy trade-off**

Why our collaborators are excited about this new design?
- **This design is simpler to comprehend and implement because it overcomes the computational and implementation complexity that plagues existing Bayesian phase I/II dose-finding designs**



Target Toxicity Rate	0.2	0.25	0.3	0.33	0.35	0.4
Escalation Boundary, λ_e	0.157	0.197	0.236	0.260	0.276	0.316
De-escalation Boundary, λd	0.238	0.298	0.359	0.395	0.417	0.48

ACTIVITIES

Biostatistics Walk-In Clinic

Aim: Aid researchers with statistical queries and codes

Format: Core members take turns to attend and answer questions

Meeting Information: 1-2 pm every 3rd Wednesday of the month on Zoom.

Co-Organizers: Seungjun Ahn and Grace Van Hyfte

Scan this QR code to register for a particular date and to let us know about your project and questions.

Biostatics Design and Analysis Workshop

Aim: To provide a forum for statistical collaboration on the development, design, and analysis of I-IIT protocols

Format: All core members meet to review, critique, and enhance protocol design and analysis plan; trainees and new members attend for learning through discussion

Meeting Information: 11-12 pm every Thursday on Teams

Co-Chair: Erin Moshier and Marcio Diniz

Seminar Series (Jointly sponsored with Institute for Health Care Delivery Science)

Aim: A live presentation of a set topic where all participants can ask questions and interact to gain a better understanding.

Format: All core members join to present or listen to external speakers

Meeting Information: 12-1 pm every other Wednesday of the month on Zoom.

Co-Organizers: Himanshu Joshi and Deukwoo Kwon

VISIT OUR WEBSITE

Scan the above QR code to visit our new website and access a PDF of this poster.