

# Biostatistics Shared Resource Facility



Mount Sinai *The Tisch Cancer Institute*

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

## BACKGROUND

- The inherently multidisciplinary nature of cancer research often presents unique challenges in study design and analysis.
- Biostatisticians play a pivotal role in addressing these challenges through various contributions, such as:
  - Efficiently designing studies to test relevant hypotheses;
  - Guiding the development of suitable databases;
  - Ensuring the feasibility of proposed analyses;
  - Analyzing study data and providing insightful interpretations;
  - Innovating with novel methodologies for study design and analysis.

## SERVICES









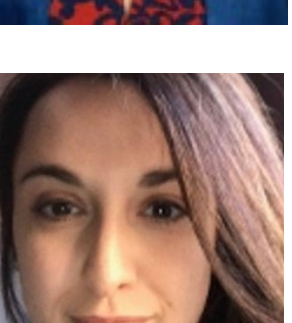

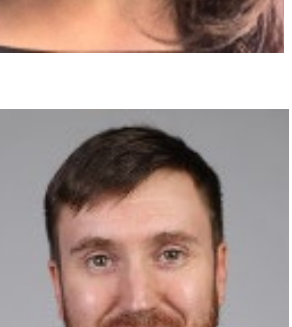

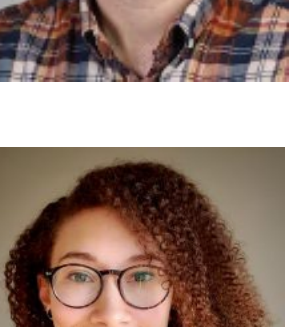
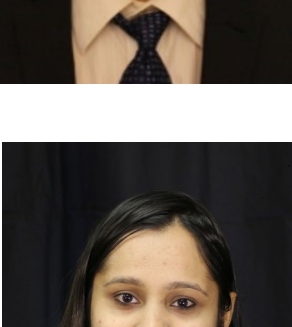

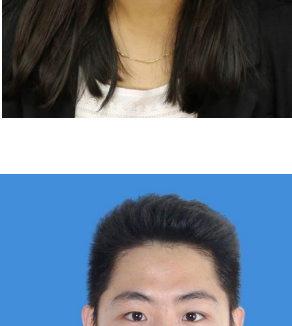
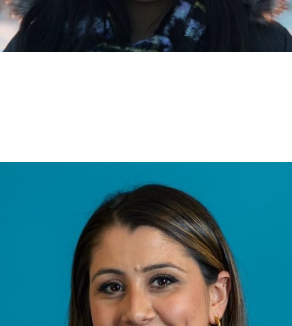
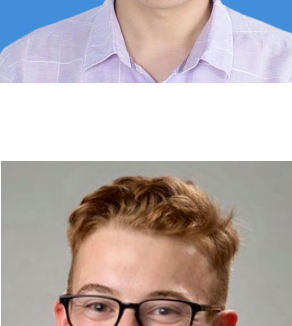
### Services Supported by NCI-CCSG (Free of Charge)

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

 <p><b>Erin Moshier, MS</b> Managing Director Group-based trajectory modeling</p>	 <p><b>Marcio Diniz, PhD</b> Co-Director Bayesian clinical trial design</p>
 <p><b>John Mandeli, PhD</b> Associate Professor Pilot / Feasibility study design</p>	 <p><b>Madhu Mazumdar, PhD</b> Co-Director Pragmatic clinical trial design</p>
 <p><b>Deukwoo Kwon, PhD</b> AD, AMC, Associate Professor Clinical trial design with external control</p>	 <p><b>Himanshu Joshi, PhD</b> Assistant Professor Predictive modeling and cancer genomics</p>
 <p><b>Parul Agarwal, PhD</b> Associate Professor Administrative data (MarketScan)</p>	 <p><b>Lihua Li, PhD</b> Associate Professor Casual inference in observational studies</p>
 <p><b>Francesca Petralia, PhD</b> Assistant Professor Bayesian algorithm development for -Omics data</p>	 <p><b>Seungjun Ahn, PhD</b> Assistant Professor Differential network analysis for -Omics data</p>
 <p><b>Lewis Tomalin, PhD</b> Assistant Professor Bioinformatics, Computational Biology</p>	 <p><b>Chen Yang, PhD</b> Biostatistician II Cluster randomized trials</p>
 <p><b>Grace Van Hyfte, MS</b> Biostatistician II Longitudinal biomarker and time-to-event joint modeling</p>	 <p><b>Mayuri Jain, MS</b> Biostatistician II Geographical spatial data analysis</p>
 <p><b>Weijia Fu, MS</b> Biostatistician II Multi-omics data analysis</p>	 <p><b>Tianxiang Sheng, MS</b> Biostatistician I Quality Improvement</p>
 <p><b>Karni Bedirian, MS</b> Biostatistician I Shiny apps and R-packages</p>	 <p><b>Nicklas Klepser, MPH</b> Research Coordinator I</p>

## 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

## STATE-OF-THE-ART STATISTICAL METHODS

### I-IIT designed with Bayesian trial designs

**Goal:**

- To assess the safety and efficacy of a combination regimen for patients with Relapsed and/or Refractory Multiple Myeloma.

**Why this design is most optimal?**

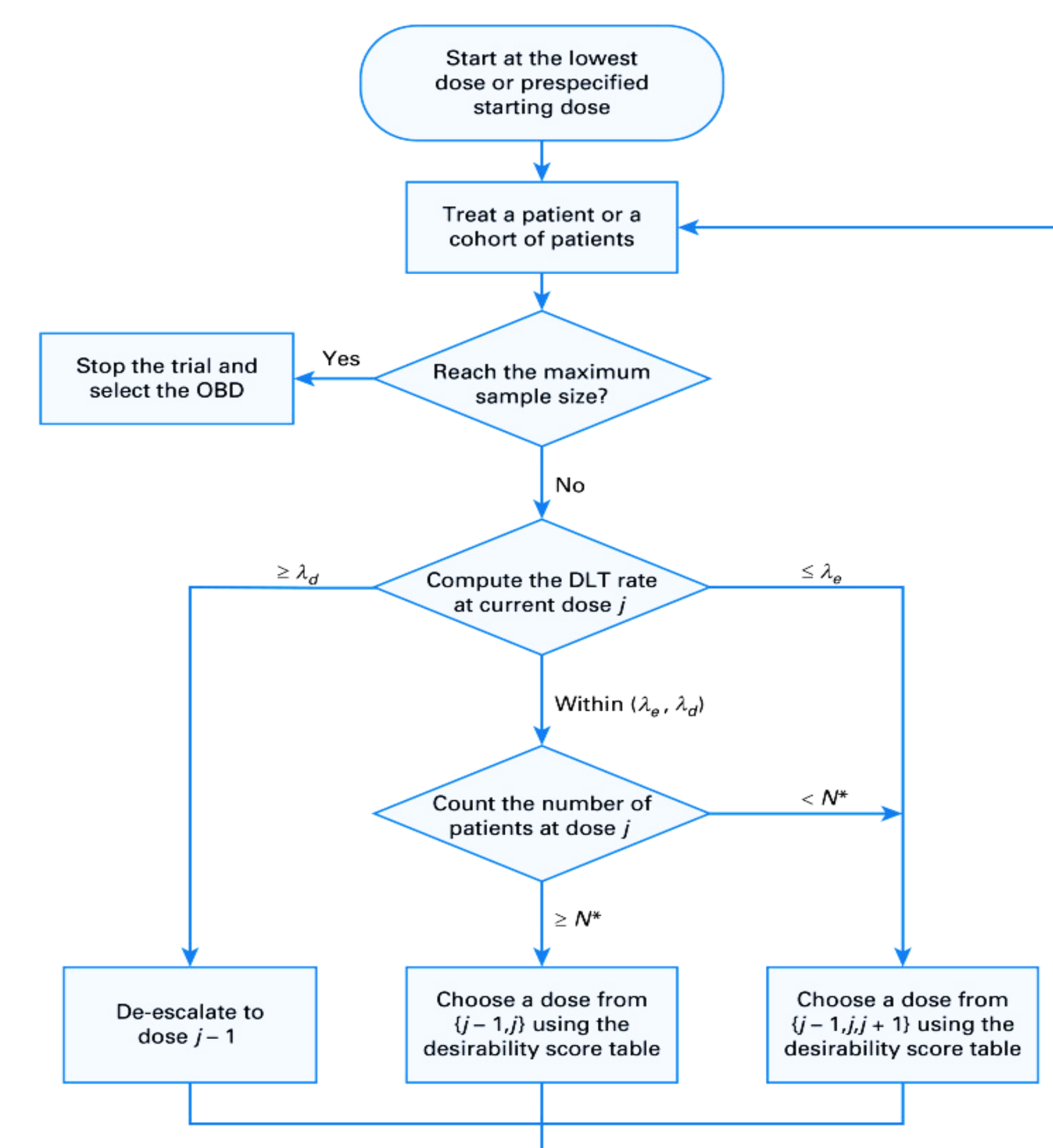
- Maximum tolerated dose (MTD) may not be the optimal dose for treating patients on novel therapies whose efficacy does not increase with dose escalation.
- Identifying the optimal biologic dose (OBD) that optimizes patients' risk-benefit trade-off becomes the target
- BOIN12 design is most optimal for 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


**Selection of ongoing trials with Bayesian designs:**

- ImeTELstat with venetoclax Or azacitidine in acute MyEloid leukemia in Relapse  
PI: Douglas Tremblay
- A Phase I/II Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of the combination of oral ON 123300 and dexamethasone in Patients with Relapsed and/or Refractory Multiple Myeloma  
PI: Adriana Rossi
- A Phase II Clinical Trial of Atezolizumab and Bevacizumab in Combination with Y90 Radioembolization for Patients with Hepatocellular Carcinoma for Liver Transplantation  
PI: Parissa Tabrizian



## 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:** Madhu Mazumdar and Nicklas Klepser
- Scan this QR code** to register for a particular date and to let us know about your project and questions.
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### Biostatistics 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.

## VISIT OUR WEBSITE



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