MGH Biostatistics: Creating Opportunities for Collaboration

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MGH Biostatistics Mission

- MGH Biostatistics aims to engage in impactful transdisciplinary partnerships involving quantitative methods in public health and biomedicine.
- We collaborate with MGH investigators on the development, application and evaluation of rigorous statistical and data science methods to define and address a broad range of hypothesis-driven and exploratory research questions across the translational spectrum.
- Translating analytic findings into clinically meaningful discoveries is at the core of our efforts and, to this end, we are deeply embedded in collaborative research teams allowing us to gain and hone subject matter expertise



Data Coordinating Centers Novel Biostatistics Methods Research

MGH Biostatistics Snapshot

Biostatistics 2021 Snapshot





63 Total (including 21 new) Members

Biostatistics 2021 Snapshot







Biostatistics Highlights Collaborative Research Partnerships







ORIGINAL ARTICLE

Trial of Sodium Phenylbutyrate–Taurursodiol for Amyotrophic Lateral Sclerosis

Sabrina Paganoni, M.D., Ph.D., Eric A. Macklin, Ph.D., Suzanne Hendrix, Ph.D., James D. Berry, M.D., Michael A. Elliott, M.D., Samuel Maiser, M.D., Chafic Karam, M.D., James B. Caress, M.D., Margaret A. Owegi, D.O., Adam Quick, M.D., James Wymer, M.D., Stephen A. Goutman, M.D., <u>et al.</u>

HEALEY ALS Platform Trial Pls M. Cudkowicz & S. Paganoni Sean M. Healey & AMG Center for ALS

- Statistical design and analysis support
- Multiple regimens enter and exit over time with shared placebo across all regimens
- 4 active regimes; 2 completed enrollment; 1 launching in November; first 3 to lock in May/June 2022



Fitbit Heart Study

PI S. Lubitz

- Single-arm remote clinical trial examining the validity of a novel PPGbased software algorithm for detecting AF
- 455,699 participants enrolled (May 2020 to October 2020)

Biostatistics Highlights Data Coordinating Centers





PETAL NETWORK

Prevention & Early Treatment of Acute Lung Injury

Effect of Hydroxychloroquine on Clinical Status at 14 Days in Hospitalized Patients With COVID-19 A Randomized Clinical Trial

Wesley H. Self, MD, MPH¹; Matthew W. Semler, MD²; Lindsay M. Leither, DO^{3,4}; et al

» Author Affiliations | Article Information

PIs T. Thompson & A. Foulkes Authorized budget: >\$55 million

- Data and Clinical Coordinating Center (CCC) for the PETAL Network (52 hospitals across 12 clinical sites)
- Led five RCTs in acute respiratory distress syndrome and COVID in past five years.
- Serves as a critical network for patient accrual for ACTIV-3 and ACTIV-4.



PIs A. Foulkes, S. Murphy & E. Karlson Authorized budget: >\$50 million

- Data Resource Core for the NIH RECOVER Initiative
- Partnership between MGH, BWH, HMS and HSPH
- >50 DRC team members



Three observational cohort studies (Adult, Pediatric and Autopsy)

- >250 clinical sites
- >30K acute and post-acute participants



Principal Goals of RECOVER:

- Determine factors contributing to PASC and PASC recovery including demographic, biological and social determinants of health
- 2. Characterize the effectiveness of pharmaceutical and nonpharmaceutical interventions on likelihood of PASC and time to PASC recovery.

- Unravel the causal mechanisms between infection, post-acute sequelae, organ dysfunction and other outcomes.
- Understand how demographics, biological factors and SDoH modify intervention effects and underlying biological mechanisms.





Timeline for RECOVER Launch

2021

14 New RECOVER Hires in MGH Biostatistics 20

2022

Mar	Apr May	Jun Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
0	0	0	0		0	0	0	0	0
NIH OTA ROA for Cores & Clinical Sites	DA MGB / NIH & Negotiations es		Protocols Finalized			Adult Cohort Pe enrollment begins		ds and Autopsy Cohort enrollment begins	
N Appl Sub	1GB lication mitted	MGB Receives NOA	Ce	entral REDCa Created	р		First USIN Fo	or Adult Co	hort

Biostatistics Highlights Independent Methods Research

Causal Inference Methodology

 Develop and apply causal inference methods in environmental epidemiology

NIH DIRECTOR'S

INDEPENDENCE

EARLY

AWARD

 Applications include air pollution and epigenomics, MS relapse, gut microbiome, COVID-19, ASD

Dr. Marie-Abele Bind (NIH DP5)



Multi-Level Omics Data

- Develop and evaluate principled statistical methods for interrogating the mechanistic underpinnings of genetic and genomic associations with complex disease traits
- High-dimensional data methods for multiple biomarker investigations
- Methods for handling time-varying and irregularly spaced biomarkers

Dr. Andrea Foulkes (NIH/NIGMS R01)



New Initiatives and Opportunities for Engagement



Dustin Rabideau, PhD

Associate Director Biostatistics and Strategic Initiatives MGH Biostatistics

Instructor in Investigation, MGH Instructor in Medicine, HMS







New Initiatives



- 1. Faculty Recruitment
- 2. Student Engagement
- 3. Support for MGH Investigators

Biostatistics Faculty Search





- Design/analysis of randomized trials
- Competing risks survival analysis
- Measurement error
- Causal inference
- Cost-effectiveness analysis
- Network analysis
- Cluster randomized trials
- Observational studies
- Electronic health records
- Medical image data



Student Engagement



- 10 biostatistics students from HSPH joining MGH Biostatistics, Spring 2022
- Diabetes, COVID-19, Bipolar Disorder, ALS, Environmental Health, Biostatistics
- Capstone student research symposium in May 2022
- Led by **Tanayott Thaweethai**, PhD, Associate Director, Biostatistics Research and Engagement, MGH



- 1. Data Coordinating Center Applications
- 2. Workforce Development Practices
- 3. Applied Biostatistics Seminar Series
- 4. Communications and Outreach

Support for MGH Investigators





MGH Biostatistics Website





We turn data into actionable clinical knowledge



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https://biostatistics.massgeneral.org/

MGH Biostatistics Website





MGH Biostatistics provides support to investigators in the design and analysis of research studies, as well as long-term scientific collaboration and data coordination for large, multi-center research programs.

Use the button below to initiate a request for a consultation with MGH Biostatistics. The information will be reviewed and a member of our team will contact you. Please note: These consultation services are typically available to investigators at MGH only.

Request a Consultation

Study Development And Design

GENERAL HOSPITAL

Data Collection And Coordination

Analysis

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Thanks!



Biostatistics Associate Directors:

Hang Lee, PhD Associate Director Collaborative Research and Consulting Services

Tanayott Thaweethai, PhD Associate Director Biostatistics Research and Engagement Special Thanks:

Maurizio Fava, MD Director, Division of Clinical Research, MGRI Vice Chair, Executive Committee on Research Chief, Department of Psychiatry

Harry Orf, PhD Senior Vice President for Research Mass General Research Institute

Merit Cudkowicz, MD, MSc Chair, Executive Committee on Research Chief, Department of Neurology

Katrina Armstrong, MD Chief, Department of Medicine



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