**Study Title**
Improving the conduct of clinical trial research through validation of a patient-centered approach to neurocognitive assessment

**Abstract**
Despite calls for inclusion of neurocognitive assessment in clinical trials, there are logistical challenges associated with existing measures (e.g., intensive examiner training, lengthy in-person test administration). In-person assessment also reduces inclusion of participants living in remote areas or with transportation limitations. This barrier may drive existing disparities deeper among rural participants who are underrepresented in clinical trials. Self-administered, online delivery of neurocognitive assessment has the potential to address these barriers. We will validate a self-administered online neurocognitive assessment battery (www.testmybrain.org) compared to gold standard neuropsychological measures. We will also demonstrate acceptance of this approach in a group of patients with diabetes and diabetic kidney disease as an initial use-case. This population has a high rate of neurocognitive impairment that is associated with both disease outcomes and treatment adherence. Our hypothesis is that self-administered online neurocognitive assessment is acceptable and psychometrically valid when compared to in-person neuropsychological measures. We will use a counterbalanced, within-subjects design comparing the online neurocognitive assessment battery to traditional in-person neuropsychological tests in patients recruited from Providence Health Care. The goals of this project are to evaluate 1) acceptability (preference and satisfaction) and 2) psychometric properties (reliability, convergent/discriminant validity and ecological validity) of self-administered online neurocognitive assessment compared to traditional neurocognitive assessment in adults with diabetes and diabetic kidney disease. The results will make routine assessment of neurocognitive outcomes in clinical trials possible, leading to new insights into neurocognitive effects and/or intervention mechanisms that would have otherwise been undetected.
**Study Title**  
Penalized regression modeling with knockoff selection to incorporate historical data for clinical trials with survival outcomes

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**Abstract**  
Studying uncommon disease populations such as leukemia and lymphoma with survival outcome data is challenging due to possibly small sample sizes and difficulties in patient recruitment. To overcome these barriers, clinical trials (CT) in rare diseases can leverage historical data on the control therapy, allowing a larger portion of the recruited subjects to be assigned to the novel therapy. Although using historical data (HD) may increase statistical power or reduce the required sample sizes for the study, it faces several challenges to use in practice. Acceptable HD, that is, HD exchangeable for randomized CT data, need to have the same features as CT in terms of the treatment, patient eligibility, patient characteristics, study centers, among others. However, HD and CT may not be exchangeable due to differences in baseline characteristics, covariate effects, study time, and study centers between the sources. Another challenge investigators frequently face with survival data is inaccurate records on time of the outcome of interest. For example, the complications after hematopoietic stem cell transplantation (HCT) to treat leukemia are evaluated during scheduled follow-up assessments or when patients show symptoms. Thus, these events are likely to be recorded after the event happened, which results in interval-censored data. Statistical methods to borrow information from HD for interval-censored data are largely ignored in current literature. Therefore, we propose a statistical method which determines the comparability between HD and CT parameters for interval-censored data so that it can improve parameter estimation efficiency when HD and CT have comparable parameters. Our proposed models will account for matching between HD and CT patients as well as potentially differential interval censoring between HD and CT.
**Study Title**
A Data-driven Approach to Unravelling the Contextual Social Determinants of Health that Drive Racial/Ethnic Health Disparities

**Abstract**
Current measurements and methods for investigating the role of SDoH in racial/ethnic health disparities have focused extensively on individual-level SDoH (e.g., income, education, health insurance, housing, transportation and social support) that are measured at single time-points in the patient’s life. The causes of these individual-level SDoH, however, are rooted in the structural conditions of the places where people are born, live, learn, work, play, worship, and age. We refer to these place-based structural conditions as the contextual SDoH. It is believed that these contextual SDoH are predominantly prevalent in the communities where racial/ethnic minorities live. Contextual SDoH can drive racial/ethnic disparities in health behaviors and outcomes via direct and indirect pathways that involve the alteration of the distribution of known individual- and healthcare system/organizational-level risk factors of health behaviors and outcomes between racial/ethnic groups. In order to empirically test these hypotheses, one must be able to measure the contextual SDoH that are associated with the outcome of interest. For this proposed project, we will use racial/ethnic disparities in antihypertensive medication (AHM) treatment nonadherence to illustrate the need for developing rigorous methodologies for measuring contextual SDoH to advance health disparities research.