collected315 samples from escitalopram-treated patients (N=288) and 265 samples from sertraline-treated patients (N=255). In youth, escitalopram and sertraline exposure (concentrations over time) and specific pharmacokinetic parameters (e.g., clearance) were influenced by CYP2C19 phenotype, concomitant CYP2C19 inhibitors, and patient-specific characteristics. Escitalopram and sertraline concentrations from remnant blood samples were 3.98-fold higher and 3.23-fold higher, respectively, in poor metabolizers compared to normal metabolizers (escitalopram, $p<0.001$) and compared to normal, rapid, and ultrarapid metabolizers combined (sertraline, $p<0.001$). DISCUSSION/SIGNIFICANCE: Combining remnant blood sampling with pharmacogenetic-integrated EMR data can facilitate large-scale population PK analyses of escitalopram and sertraline in youth. This real-world approach can be used to rapidly develop precision SSRI dosing strategies, including slower titration and reduced target doses in CYP2C19 poor metabolizers.

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Investigations of Clinical and Translational Science Roadblocks: a Survey of a Private Medical School and a Large Public University

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OBJECTIVES/GOALS: Clinical and translational science needs to address roadblocks to translational processes. We conducted a survey at two institutions, a private medical school and a large public university, to understand the frequency and distribution of barriers and roadblocks to research. METHODS/STUDY POPULATION: We reviewed the literature to compile a pool of barriers and roadblocks and convened a panel of relevant stakeholders to develop a 20-item questionnaire. Survey respondents were asked to select and prioritize the five leading clinical and translational roadblocks, provide information regarding their academic degrees and rank/position, complete open-ended items regarding their areas of research, and optionally add additional remarks in a comment box. The survey was disseminated in August 2022 via REDCap to faculty and staff with active research protocols at Baylor College of Medicine and the University of Houston. RESULTS/ANTICIPATED RESULTS: In total, 227 respondents completed the survey. Their disciplines were basic science (29.5%), translational research (52.9%), clinical research (55.5%), community-engaged research (9.7%), and educational research (9.7%). Respondents identified 1) lack of access to trained research coordinators, 2) lack of understanding about different resources that facilitate research, 3) complex regulatory environment and delays, 4) fragmented infrastructure for administrative and fiscal processes, and 5) inadequate funding for pilot projects to foster new research. Other roadblocks included lack of established community stakeholder partnerships, inadequate access to medical record data, and limited biostatistical support. In the comments, several respondents noted that all items included were important. DISCUSSION/SIGNIFICANCE: Research workforce recruitment/training was the highest priority followed by lack of access to information and administrative bottlenecks. We are building an online portal to increase awareness and simplify access to competency-based training and research services. Initiatives are underway to address other roadblocks.

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Feasibility of a Home-based Physiotherapy Program to Increase Physical Activity Levels in Older Adults with Diabetes Mellitus

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OBJECTIVES/GOALS: The objective of this study is to assess the feasibility and preliminary impact of a physiotherapy protocol for developing an individualized home-based physical activity program to increase physical activity (PA) levels in sedentary older adults with Type II Diabetes Mellitus (T2DM) living in Puerto Rico (PR). METHODS/STUDY POPULATION: This will be a pilot study with two phases. In phase 1, we will design a novel patient-centered home-based PA program protocol for adults ≥65 years with T2DM based on the Information-Motivation-Behavioral Skills model. Its content validity will be assessed through focus groups with 10 experts and 10 older adults and analyzed using a directed content analysis. Phase 2 we will be program implementation using a one-group, repeated measures design with 12 adults ≥65 years with T2DM. PA levels will be assessed by recording active minutes with a Fitbit. Risk of falls, balance, strength, and physical function will be assessed through standardized tests validated for this population. Statistical analysis will include descriptive statistics, comparisons via chi-square/Fisher's exact test, and non-parametric tests. RESULTS/ANTICIPATED RESULTS: We expect to recruit a minimum of 12 participants and to administer the program for 12 weeks at a frequency of two visits per week. We anticipate that implementing and supervising the home-based PA protocol will be feasible as determined by recruitment and retention rates, patients' satisfaction, and compliance with the program. We also expect that this protocol will increase physical activity levels, improve general strength, balance, physical function, and reduce the risk of falls in sedentary older adults with T2DM. DISCUSSION/SIGNIFICANCE: As the third cause of death in PR, T2DM represents a public health challenge. An effective home-based PA program may decrease morbidity and mortality rates in older adults by increasing PA and functional health. This study will provide data for planning a randomized controlled trial to assess its effectiveness in the outcomes of interest.

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Two Newly Developed Frontiers CTSI Applications to Support Recruitment and Trial Management: The Frontiers Trial Finder Mobile App and a Predictive Accrual Web-based App

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OBJECTIVES/GOALS: Frontiers CTSI developed applications to ensure its science teams have technological tools to advance their community engagement and trial management. The Trial Finder app is a mobile application that allows users to navigate available trials. The Accrual app will help study teams monitor their

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recruitment performances in real time. METHODS/STUDY POPULATION: The Data Science team at the University of Kansas Medical Center (KUMC) had previously developed similar applications for The University of Kansas Cancer Center. Both retrieve information from KUMC's clinical trial management system and ClinicalTrials.gov. This was replicated to include KUMC Pulmonary Critical Care (PCC) and KUMC Neuromuscular (NM) trials. Frontiers CTSI is working with both groups for piloting and feedback. Recruiting and marketing strategies for investigators to add their trials to both apps will be done through existing communication channels and be highlighted on Frontiers trial resource website. Recruiting and marketing strategies of the Frontiers Trial Finder app to the external community will have a focus on, but not limited to, paid social media advertising. RESULTS/ANTICIPATED RESULTS: The Trial Finder app can help providers search for trials their patient may be eligible for during clinic visits and to engage with the community by allowing anyone to download and browse on their Android/iOS device. Built in REDCap forms are used to capture contact information. The Accrual app is a web-based application that helps study teams monitor their recruitment performances in real time and provide an opportunity to adjust strategies. It uses an in-house algorithm to predict if trials will meet timeline goals. This data is conveniently laid out on a single web page so that science teams can overview all their trials' recruitment performances simultaneously. The next phase of developing these applications is to market their use within Frontiers CTSI and its community catchment area. DISCUSSION/SIGNIFICANCE: Through collaboration, Frontiers CTSI is developing resources to support community engagement and trial management. New innovative applications like these ensure all the main stakeholders involved with clinical trial execution are always engaged and have access to iterative contemporary technologies that support their research.

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Novel approach for childhood Sjögren's Disease therapies: multistakeholder design of a series of N-of-1 trials

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OBJECTIVES/GOALS: Childhood Sjögren's disease (cSD) is a rare autoimmune disease. Despite the profound impact on children and their families, pediatric-specific clinical trials to inform therapeutic strategies in cSD are lacking. In 2022 we participated in the Trial Innovation Network (TIN) Design Lab with the purpose of designing a series of N-of-1 trials for cSD. METHODS/STUDY POPULATION: New medications have the potential to be safe/effective treatments for cSD but must be evaluated in randomized trials. To overcome limitations of traditional parallel-group designs given the rarity of cSD, we developed an N-of-1 trial approach. Our proposal was selected by the Tufts TIN Design Lab. The Design Lab multi-stakeholder process involved parents of and patients with cSD, pediatric and adult rheumatologists, and experts in clinical trial design and outcomes. We engaged all stakeholders in protocol development to maximize the impact of the proposed approach on clinical care, ensure a successful recruitment plan, and inform the choice of endpoints as there are no widely accepted cSD outcome measures to determine treatment efficacy. RESULTS/ANTICIPATED RESULTS: Using the Design Lab methodology, we clarified the N-of-1 study goals and engaged in an iterative process to develop a "briefing book" that ensured a sound premise for our study. We reviewed and accumulated published literature to support our focus on mucosal/glandular manifestations, identified potential interventions to be used in the N-of-1 trials, and enumerated possible outcomes, including outcomes important to patient/parents. This work culminated in a full-day Design Lab event that included multiple stakeholders who provided expertise from different perspectives on the full drug development pathway. Study design feedback focused on three specific areas. 1) Inclusion and exclusion criteria; 2) Identification of outcome measures; 3) Treatment and washout periods. DISCUSSION/SIGNIFICANCE: To address the critical need and move treatment of cSD forward, we are designing a prototype N-of-1 trial in children with rheumatic disease. We will continue to engage stakeholders by using a series of Delphi surveys and an in-person meeting to create composite outcome measures to test cSD therapies in personalized trials.

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Using the Health Stigma Discrimination Framework for Understanding Stigma in the Context of Sexual Assault

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OBJECTIVES/GOALS: This theory analysis aims to evaluate a middle-range framework, the HSDF1, in the context of sexual assault stigma incorporating the myriad levels within within culture and society through which stigma can occur and be reinforced. METHODS/STUDY POPULATION: Databases: PubMed, CINAHL, EMBASE, Google Scholar, Organization websites, Citation searchesn = 32Mark Risjord's "Middle-Range Theories as Models: New Criterion for Analysis and Evaluation" (2019) RESULTS/ANTICIPATED RESULTS: The innovative approach of the HSDF guides understanding of sexual assault stigma in a holistic way, incorporating individual and institutional stratum of the phenomenon. Understanding through integration of this theoretical framework alongside current knowledge may more succinctly inform trauma-informed care for survivors, policy, and cultural awareness for nurses, healthcare providers, police, social workers, and myriad others with whom survivors interact. DISCUSSION/SIGNIFICANCE: Applying the HSDF framework to sexual assault stigma could help break down barriers and raise survivors out of stigmatization, affecting population health through reduced negative health sequelae experienced by survivors.

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Honest Broker Tool to Automate Data Extraction from Clinical Research Data Warehouse

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OBJECTIVES/GOALS: To describe an Honest Broker (HB) tool and workflow integrated with the Institutional Review Board (IRB) to automate requests, approvals and delivery of both de-identified and identified data extractions from a clinical research data warehouse (CRDW). METHODS/STUDY POPULATION: The HB tool

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