

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 searches = 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

has predefined domain tables and is closely integrated IRB for quick and easy review and approval. Investigators can access patient data using query tools, barcodes from biospecimens or build a query in TriNetX and provide the patient list as an input for the HB tool. For de-identified data extraction, the required data domain tables and date ranges can be selected and submitted in the HB tool. For identified data extractions, investigators with an approved IRB protocol can enter the protocol number and the approved date range in the HB tool. This request is automatically forwarded to the IRB for review. RESULTS/ANTICIPATED RESULTS: For de-identified data extraction, an email alert is automatically sent to the investigator once the data extract is completed. For identified data extraction, if IRB approves the request, an HB is immediately notified to release the data. Data release triggers two emails to the investigator: (1) a link to an encrypted zipped file with the requested data, and (2) a password to unlock the encrypted file. If the request is denied, the IRB sends an email to the investigator with the reason for denial and options for remediation. The entire HB workflow is accomplished in a secure environment with an audit trail from the initial data request to data download by the investigator. Since the launch of the HB tool, the time from data request to delivery is approximately an hour for deidentified data and 24 hrs for identified data. DISCUSSION/SIGNIFICANCE: The HB tool has increased successful data delivery in support of publications, grant submissions, and clinical trial recruitment. Optimization of data extraction from the CRDW through automation and integration with the IRB can minimize interaction with data analysts and IRB staff, thus accelerating the conduct of clinical research.

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### Investigating the minimal requirements for startup procurement by healthcare institutions in Ontario, Canada

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OBJECTIVES/GOALS: The primary goal is to understand the challenges and barriers associated with the procurement of innovative technologies. Specifically, our research will answer the following question: what are the minimal requirements for a startup's solution to be procured by an Ontario healthcare institution? METHODS/STUDY POPULATION: Participants will include procurement professionals at startups, healthcare institutions, and procurement facilitating agencies. Semi-structured interviews will be conducted in order to understand different procurement pathways and the possible procurement related gaps or barriers that startups face. Through qualitative ethnographic methods, participant interviews will characterize existing relationships and examine the rationale behind startup procurement decision-making. Data collection will include recordings, verbatim transcripts, and researcher field notes. Through inductive qualitative analysis, the data will be examined to build an intervention to assist in startup procurement. RESULTS/ANTICIPATED RESULTS: Our investigation will yield insight into expectations between hospital procurement requirements and startup procurement. The qualitative analysis will identify targets for engagement, and appropriate actors that can bridge gaps. Our results will identify pathways for procurement and the minimal

procurement requirements to aid startup procurement planning. Our research will support innovators by delivering an intervention that will enable easier implementation of market ready solutions in a Canadian context. In line with principles from the National Center for Advancing Translational Sciences, this research can be used towards enhancing efficiency, speed of translation, and innovation. DISCUSSION/SIGNIFICANCE: We will contextualize the needs of start-ups and empower them to understand their procurement ecosystem. Facilitating better navigation of the procurement space allows for innovators to present solutions that healthcare organizations can adopt, resulting in improved clinical and patient outcomes.

## Diversity, Equity, Inclusion and Accessibility

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### Incorporating Health Equity, Diversity and Inclusion Professional Development During Community Advisory Board Meetings

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OBJECTIVES/GOALS: Incorporating health equity, diversity, and inclusion (HEDI) development during community advisory board meetings is essential for ensuring that perspectives of all community members are considered, that health research is centered on the experiences of historically marginalized groups, and organizational strategies align with the community. METHODS/STUDY POPULATION: All IN for Health is a public engagement program that promotes health and research literacy, seeking to increase the public's understanding of the role and value of research in improving health. It is guided by an active CAB providing advice on strategic directions, feedback to all efforts, contributing ideas, priorities, and most importantly, accountability. In 2023, ALL IN for Health started to incorporate HEDI professional development during staff team meetings and most recently, into our quarterly CAB meetings. Initially, the CAB was asked to provide feedback about talks and potential presentations related to health-research, sponsored, and shared by All IN for Health. During this exercise, board members were asked to provide HEDI topics of interest. Their responses informed a plan for team and board members. RESULTS/ANTICIPATED RESULTS: Some of the topics suggested by board members include: understanding health equity in relation to research studies and protocols, and topics specific to health research such as: health care access for rural areas and vulnerable populations, culture-based attitudes and beliefs and how they impact decisions related to health care, being aware of limitations certain communities have and what they may not have access to. The initiative was positively received and unanimously adopted. We hope to introduce the HEDI integration model for CABs at this conference. (Conceptual Model attached). DISCUSSION/SIGNIFICANCE: It is important to learn and grow alongside our community members. Such practice is bound to sustain partnerships that promote health equity, and exemplify meaningful community engagement, bidirectional learning, and a shared leadership model. By consistently incorporating and prioritizing HEDI, HAB can contribute to more equitable initiatives.