

day-to-day clinical care for these infants. Implementation of this novel protocol will promote the early diagnosis and referral to treatment for NDD.

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### Implementation of Consent-to-Contact (CTC) initiative at an Academic Medical center: Initial operationalization and lessons learned

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**OBJECTIVES/GOALS:** The objectives of this presentation are to discuss 1) the implementation of Consent to Contact at an Academic Medical Center; 2) the access to lists of potential participants by study teams; and 3) the challenges and adjustments made to the initial conceptualized process. **METHODS/STUDY POPULATION:** Participant recruitment is critical to the success of all research studies. It is particularly challenging when investigators do not have a patient population from which to recruit. Thus, the University of Miami launched the CTC initiative in 2016 to facilitate study recruitment. Study investigators can request access to a registry of participants who agreed to be contacted and meet the initial study eligibility criteria. A multidisciplinary Operational Committee provides oversight and regulates access to the CTC registry. **RESULTS/ANTICIPATED RESULTS:** The registry has over 110K patients who have agreed to be contacted for eligible research studies. The demographic distribution of the patients in the registry mirrors the diversity of the UHealth population. As of January 2018, when the registry became available to the research community, 25 study teams from different departments, including the All of Us Research Program, have requested potential participant lists. The process of requesting access to patient lists is adapted to studies' needs, with particular reference to sensitive populations, such as HIV/AIDS, substance abuse, etc. Results on utilization and satisfaction of the CTC initiative are being collected and will be presented. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The CTC initiative allows UHealth patients to opt-in to the registry for research studies. The Operational Committee continues to monitor the successful consent of patients to participate in individual research studies and improving the request process.

4401

### Incidence, management, and outcomes of immune-related adverse events (irAEs): an analysis of a multidisciplinary toxicity team for cancer immunotherapy related irAEs

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**OBJECTIVES/GOALS:** This study aims to assess the outcomes of a new virtual multidisciplinary immune-related toxicity (IR-tox) team implemented at Johns Hopkins Hospital. In particular, to understand if the IR-tox team's input reduced the number of inpatient hospitalizations for irAEs for referred patients. **METHODS/STUDY POPULATION:** Since August 2017, nearly 250 patient referrals to the IR-tox team have been created and stored in an electronic database. Through retrospective chart review, hospitalization and irAE management data will be collected for these patients to assess whether rates for suspected

irAEs have decreased. These rates will be compared against historical controls. We will assess the features of hospitalized patients, their immunotherapy regimens, and management to identify high-risk groups who may require early intervention. Additionally, we aim to understand what patient features are associated with IR-Tox team referral and subsequent hospitalization. **RESULTS/ANTICIPATED RESULTS:** The IR-tox team provided a new multidisciplinary channel to help physicians diagnose and manage complex irAEs. The goal of the team was the reduce the number of irAE-related hospitalizations as, historically, 85% of high-grade irAEs have required hospitalization. A clinically meaningful reduction is defined as lowering the hospitalization rate to 75%. Planned analyses includes calculating the hospitalization rate, using descriptive statistics to summarize patient features, multivariate analyses to understand features associated with both IR-Tox team referral and hospitalization, and computing the relative risk reduction to assess the efficacy of subspecialist referral implementation. **DISCUSSION/SIGNIFICANCE OF IMPACT:** IrAEs are challenging to diagnose and treat. They contribute to a notable proportion of hospitalizations in those treated with immunotherapy. With expanding use of immunotherapy, widespread implementations of IR-Tox teams may help reduce hospitalizations and costs associated with care for irAEs.

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### Infusing a CTSA Program with Causal Pathway Thinking to Transform Evaluation from Operations to Impacts

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**OBJECTIVES/GOALS:** Innovations with positive health impact are a high priority for NCATS and CTSA. Program design that uses the Causal Pathway approach incorporates performance indicators that assess impact. We applied Causal Pathway thinking to an ongoing national program to enhance the evaluation of program impact. We report Lessons Learned. **METHODS/STUDY POPULATION:** We conducted a day-long onsite workshop to introduce the model to the project team, build capacity, and map the existing program elements to Logic Models representing program Specific Aims. A local Causal Pathway (CP) champion was identified. Alignment of the Logic Models with the CP approach (input→activities→ outputs→effects/impact) developed iteratively through biweekly, then monthly conferral among stakeholders. Key tasks included distinguishing among activities, outputs, and effects (impacts), and identification of performance indicators for each stage of the Causal Pathway. Visualization tools and an additional late stage half-day workshop were used to foster consensus. Implementation of the CP model tested the feasibility of collecting specific indicators and prompted model revisions. **RESULTS/ANTICIPATED RESULTS:** Program leadership and team members (n = 30) participated in the kick-off workshop. Four Specific Aims were mapped to Logic Models. Multiple Causal Pathway (CP) diagrams, one for each project in the program, were developed and mapped to Aims. Alignment of CP threads to Aims and identification of performance indicators required iteration. CP threads converged onto common final Impacts, sometimes crossing to another Aim. Performance indicators for operations were readily accessible to team members, and less so for impacts. Assumptions about program effects were subjected to specific indicators. Over time, Leadership noticed more expression of CP thinking in daily activities. New projects developed during this period

incorporated the CP approach. Teams were able to streamline and simplify Logic/CP models. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Through capacity-building and mentored exercises, an innovation team was able to infuse CP thinking into the evaluation of their ongoing program. The CP approach to design and evaluation maps progress and indicators across the life of a program from initial activities to its ultimate impact.

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### Lessons learned from implementing Quality Improvement (QI) in academic clinical research setting

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**OBJECTIVES/GOALS:** We describe here the implementation of a pilot Quality Improvement (QI) program in clinical research processes in order to facilitate translation from bench to community. This presentation will also discuss challenges encountered by the research teams during the implementation of QI activities. **METHODS/STUDY POPULATION:** Miami CTSI collaborated with University of Kansas' CTSA to test the implementation of a QI program for clinical research processes. The program has a duration of 1 year and consists of multi-modal training and coaching sessions with different research teams. Six teams comprising of Principal investigators, clinical coordinators, and regulatory specialists participated in the program based in applied clinical microsystem theory science. Team coaches and teams worked together to assess current processes, test new and improved processes, and standardize and disseminate applicable best practices of the QI program. **RESULTS/ANTICIPATED RESULTS:** The implementation of QI activities in large clinical research settings poses numerous challenges for the research team. We will present survey results from the coaching sessions and follow on feedback from the different teams involved in the program to implement the QI activities. We will describe the modifications and adjustments made to the original conceptual framework of QI program in order for it to be applicable and feasible for the settings of the University of Miami. We will provide recommendations for other academic clinical research centers that are considering implementing a QI program. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The successful adaptation of a QI process to implement in academic clinical research settings relies on early engagement of the institution leadership, careful selection of team members, as well as developing communication skills to enhance team dynamics as a clinical research unit.

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### Report from the research trenches: A mixed-methods approach to investigation of how recruitment methods, culture and collaboration impact clinical trial accrual

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**OBJECTIVES/GOALS:** The research project aimed to understand the perceived effectiveness of research recruitment methods, including informatics tool utilization, so that best practices can be established and outcomes measured longitudinally. **METHODS/STUDY**

**POPULATION:** The mixed-methods study was conducted by the Oregon Clinical and Translational Science Institute, the CTSA at Oregon Health and Sciences University. A survey, clinical trial accrual data, and interviews were used to assess the study aims. The survey asked about utilization and value of specific recruitment tools and methods. Accrual data was obtained from the clinical trial management system and analyzed using parameters from the CTSA "Accrual Metric". The metric was calculated for clinical trials enrolling during 2017. Interviews were conducted with researchers identified by the survey and over or under-enrolled accrual data, and inquired about recruitment facilitators and barriers. **RESULTS/ANTICIPATED RESULTS:** The most frequently mentioned facilitator of recruitment was direct patient contact, either in the healthcare setting (58.4% of survey respondents) or through patient outreach (32%). A lack of resources was considered a key barrier (21% of survey respondents) and a stated need (27%). Interview data expanded on these findings, as 23% of interviewees indicated a collaborative culture, which includes clinic integration, was key to recruitment success. Additionally, 20% of interviewees identified resources (i.e. funding, staff, time) as their greatest need. Notably, 13% of studies with an accrual ratio of "0" had frequent staff turnover. **DISCUSSION/SIGNIFICANCE OF IMPACT:** This approach allowed for a uniquely targeted analysis of accrual facilitators and barriers. Use of the CTSA accrual metric identified high-value interview respondents and will allow for investigation into additional accrual questions, such as the impact of funding sources and departmental factors.

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### Results of a Formative Evaluation of the Cardiopulmonary Vascular Biology (CPVB) Center of Biomedical Research Excellence (COBRE)

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**OBJECTIVES/GOALS:** Results of a formative evaluation of the CardioPulmonary Vascular Biology (CPVB) COBRE will be presented. Of interest were the quality of the overall program, satisfaction with training, mentoring, and services offered, mechanisms for communication, and effectiveness of the collaboration between junior investigators and their mentors. **METHODS/STUDY POPULATION:** Integral to this evaluation was the creation of questionnaire for junior investigators to complete that addressed four domains: 1) relationship with their mentor, 2) research self-efficacy, 3) administrative and specialty cores value, and 4) satisfaction with events and operations of the COBRE. The two co-principal investigators, program manager, and evaluator developed the 34 items comprising this instrument. The questionnaire was administered online and all eight of the current junior investigators completed the questionnaire. **RESULTS/ANTICIPATED RESULTS:** Participants were mostly satisfied with the mentoring they were receiving and the operational services of the Administrative and Lab Cores. In terms of training preparedness, these participants felt they were not as prepared as they would like for making adequate progress as an academician and did not feel prepared for managing a lab. Interestingly, these participants felt they were most prepared to develop collaborations with scholars and professionals from other disciplines, but stated they felt they were not as prepared in their abilities to build scientific collaborations. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Because a primary foci of COBRE grant mechanisms is the development of junior level investigators, evaluating their skills, mentoring experiences, and the usefulness of services is