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Applying and evaluating an enhanced "Quality by Design" program across the translational science spectrum

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OBJECTIVES/GOALS: To implement and evaluate the Quality by Design (QbD) framework integrating team science and project management to increase quality and efficiency in clinical and translational studies. Goals include achieving 80% on-time completion and sharing tools to expand QbD use across other CTSA hubs. METHODS/STUDY POPULATION: The SC CTSI launched the QbD program in 2022 to support pilot grants, KL2 Scholar projects, and other CTSI-funded studies. Program elements include 1) Design Studios, facilitated by a QbD Specialist and attended by interdisciplinary advisors, to anticipate risks to timely study completion; 2) ongoing project management with regular check-ins; and 3) team science support for multidisciplinary research teams. Study teams establish milestones and track risks across the timeline. Ongoing evaluation follows studies across a wide variety of disease areas, using mixed methods to assess feasibility, perceived value, and impact on scientific productivity and institutional culture. RESULTS/ANTICIPATED RESULTS: The QbD program has been delivered consistently, demonstrating it is feasible and well-received, with 93% of PIs reporting QbD as valuable for identifying risks and refining protocols. Early evidence suggests QbD support may reduce delays, with shorter extensions, while common barriers stemmed from institutional and administrative hurdles. PI interviews highlight QbD as a constructive framework for strengthening early planning and risk mitigation, with feedback prompting ongoing refinement such as adjusting the timing of Design studios. Anticipated results include continuous evaluation outcomes, ongoing program improvements, and broader dissemination with other CTSA hubs. DISCUSSION/SIGNIFICANCE OF IMPACT: Evaluation will clarify how QbD implementation influences study planning and risk mitigation to prevent delays. Broader outcomes will include toolkit development and fostering a culture to advance proactive, quality-focused research services across institutions.

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A showcase of dynamic collaboration among IRBs within a geographic region

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OBJECTIVES/GOALS: Navigating uncertainty with emerging technologies used in human research is an ongoing concern for HRPPs and IRBs. This poster aims to describe how collaboration between IRB Offices within a geographic region yields support to address questions and explore possible solutions in a local context. METHODS/STUDY POPULATION: The Southeastern Wisconsin, Clinical and Translational Science Institute (CTSI) includes joint faculty appointments, shared research resources, and various partnerships between researchers and the IRBs of the institutions. In response to increases in projects using AI, one of the partnering institutions inquired with partnering IRB administrators for information on their processes reviewing AI-related research and the connection resulted in monthly meetings between the IRBs. The meetings began with an AI-specific focus but have since developed into a mechanism to support researchers with group members conferring on example submissions and discussing overlapping initiatives. RESULTS/ANTICIPATED RESULTS: This effort has assisted in furthering the mission of the CTSI by lowering barriers to conducting collaborative research. The workgroup partnered to develop a guidance document for researchers seeking to utilize AI in research and for IRB members reviewing the projects. Also, several institutions adapted similar content for protocol submissions, and three implemented consistent questions within the submission forms for research involving AI. In addition, the workgroup has driven individual action at each institution and increased comfort with reaching out to one another for general guidance and advice. DISCUSSION/SIGNIFICANCE OF IMPACT: The group was successful in building resources and infrastructure around the review of research utilizing artificial intelligence. A local IRB work group has the potential to address ongoing IRB-related issues and topics within the local context of the geographical region.

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Accelerating academic innovation: Comparative insights from the translational case studies in commercialization working group

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OBJECTIVES/GOALS: To generate actionable insights into the commercialization process in academic translational science by using comparative case studies to identify strategies, success factors, and challenges across CTSA hubs, informing best practices for innovators and institutions. METHODS/STUDY POPULATION: We will employ a comparative case study approach, engaging 11

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CTSA hubs to document two or more product-specific commercialization case studies, including at least one successful and one unsuccessful example. To ensure the comprehensiveness and consistency of data collection and analysis across cases, a standardized framework developed by the TCSC WG is followed by all participating hubs for both quantitative data (e.g., milestones, funding) and qualitative insights (stakeholder interviews). Coding and downstream cross-case analysis is leveraged to identify unifying themes and discriminating factors in commercialization strategies and associations with success and failure. RESULTS/ANTICIPATED RESULTS: We aim to identify patterns, barriers, and catalysts in academic commercialization, defining key resources along with effective practices and strategies. Findings will clarify the role of CTSA hubs and their collaboration with institutional partners such as Technology Transfer. Results will highlight best practices in IP management, funding, team dynamics, partnerships, and regulatory navigation. A comparative analysis across CTSA hubs will yield a case study repository, cross-case report, educational materials, and a peer-reviewed publication. Collectively, we expect findings to provide practical guidance to NCATS and academic institutions for accelerating biomedical innovation. DISCUSSION/SIGNIFICANCE OF IMPACT: This study fills a critical gap by providing real-world, comparative insights into the commercialization process within academic medicine. Outcomes will support CTSA hubs, healthcare systems, innovators, and policymakers in improving translational efficiency and maximizing innovation impact.

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Audiological and psychosocial profile of Puerto Rican adults suffering from tinnitus

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OBJECTIVES/GOALS: The objective is to study the association of subjective tinnitus, hearing status, clinical symptoms and the psychosocial effects on Puerto Rican adults with the condition. A specific aim is to describe auditory status, tinnitus characteristics and subject's performance on the Tinnitus Handicap Inventory (THI). METHODS/STUDY POPULATION: This is a Transversal Descriptive pilot study, where 30 clinical records of adult Puerto Rican subjects diagnosed with Tinnitus on the Intramural Audiology Clinic of the Medical Sciences Campus, located at the University of Puerto Rico, during 2022 to 2024 were analyzed to establish a profile. Subjects between 21 and 64 years old from both genders were studied. This research was conducted after the Office of Research Participant's Protection-IRB of the Medical Sciences Campus of the University of Puerto Rico gave the approval. RESULTS/ANTICIPATED RESULTS: The study found that Tinnitus can have a significant impact in the individual's life. The effects were registered mainly in the following areas: •Emotional Area: Subjects reported anxiety associated to experiencing Tinnitus. •Mental Health: Subjects reported being stressed due to their Tinnitus •Cognitive Functioning: Subjects reported difficulties to concentrate, think with clarity o recall information. Also subjects indicated that Tinnitus interferes with their sleep patterns affecting rest and having negative synergic effects resulting in confusion and fatigue. The condition impacts daily living productivity as well as occupational tasks. Eighty-three percent of research participants reported that their Tinnitus interfere with household tasks. DISCUSSION/SIGNIFICANCE OF IMPACT: This pilot study adds to the body of evidence that validates the need to address Tinnitus in an integral manner treating its effects in all the physical and mental health dimensions affected by the condition. Also, the results of this study can be used to promote health plans coverage in Puerto Rico for Tinnitus assessment and rehabilitation.

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Breaking barriers and boosting efficiency: Accelerating translational science in the creation of a new academic health center

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OBJECTIVES/GOALS: This initiative accelerates translational science by integrating infrastructure, engagement, and workforce development to overcome barriers and improve efficiency in building a new academic health center. The primary objective is to overcome translational roadblocks while fostering a culture of innovation and collaboration. METHODS/STUDY POPULATION: The Florida State University (FSU) Health Research Connections ticketing and navigation system serves as a centralized system for research support, data capture, and service coordination. Pilot projects include utilizing group model building, a systems science approach, to map barriers and facilitators in community clinics; and testing community-engaged, trustworthy recruitment strategies into FSU Health Research Link, a community facing research portal. The initiative engages academic researchers, community members, healthcare providers, and trainees across Florida, adapts existing UF/FSU hub resources, and develops new resources that capitalize on FSU's strengths and needs. Evaluation applies the Translational Science Benefits Model to assess impact across domains. RESULTS/ANTICIPATED RESULTS: Preliminary outcomes from CTSA-supported initiatives at FSU demonstrate measurable progress in breaking translational barriers and boosting efficiency. The HRC ticketing system has streamlined research support. Metrics to be presented include the number of individuals enrolled in the FSU Health Research Community Portal, use of HRC tools and services, engagement in training workshops, external funding and scholarly outputs, utilization of big data, and adoption of findings into clinical practice. Findings from community-engaged recruitment pilots and trust metrics will also be presented. DISCUSSION/SIGNIFICANCE OF IMPACT: FSU Health offers a replicable model for new academic health centers, particularly relevant for newer CTSA hub partners. Embedding evaluation and engagement sets a new standard for community-partnered, efficient, and impactful translational science infrastructure and accelerates discovery into practice.

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