ITM Trial Recruitment Innovation Office

TRIO Studio Presentations and Report

- **Adding Health Equity to the Network Capacity Cluster**  
  Presented September 9, 2020
  Sherry Robison, Manager of the Institute for Translational Medicine's Trial Recruitment Innovation Office, presented the Studio topic: How Do We Add Health Equity to the Network Capacity Cluster?  
  Sherry was looking for ways to advance health equity in the megalopolis through the specific aims and tools of the Network Capacity Cluster.

- **Recruiting Diverse Participants in Research Studies**  
  Presented August 26, 2020
  Ashley Lopez, Coordinator and Honest Broker for the Institute of Translational Medicine's Trial Recruitment Innovation Office, presented the Studio topic: Recruiting Diverse Participants in Research Studies.  
  Ashley was looking for ideas to increase diversity in research studies through TRIO's Honest Broker role.

- **Improving PCP Identification Accuracy during Emergency Department Visits and Hospitalizations**  
  Presented August 12, 2020
  Laura Magda, MD, TL1 Postdoctoral Fellow at the University of Chicago, presented the Studio topic: Improving Primary Care Physician (PCP) Identification Accuracy during Emergency Department Visits and Hospitalizations.
  Laura was looking to improve Primary Care Physician (PCP) accuracy within hospitals and Electronic Medical Record (EMR) systems, as well as to help patients with complex medical care more easily identify their PCP within their own care team.

- **Addressing a Barrier to Research as the New Normal**  
  Presented July 8, 2020
  James Mulshine, MD, Associate Director of Community and Collaboration for Rush University Medical Center, presented the Studio topic: Addressing a Barrier to Research as the New Normal: Facilitating Data Sharing Through Standardizing DUA Process.
  Dr. Mulshine was looking for ways to simplify and accelerate DUA processes across the Institute for Translational Medicine through the adoption of Federal Demonstration Partnership (FDP) and Data Transfer and Use Agreements (DTUA) processes.

- **The New Normal: Getting the Word Out to Investigators and Their Study Teams**  
  Presented June 10, 2020
  Amanda Kass, Trial Recruitment Innovation Office Coordinator within the Institute for Translational Medicine, introduced the Studio topic: The New Normal: Getting the Word Out to Investigators and Their Study Teams.
  Part of The New Normal Campaign, which is geared toward normalizing participation in clinical research, is an online matchmaking portal that connects study teams to potential participants. Amanda was looking for ideas on how to recruit more studies on The New Normal matchmaking portal.

- **Utilizing e-Consent for Research Studies**  
  Presented May 27, 2020
  Tiffany Phanhdone, MD, Research Regulatory Coordinator II at Rush University Medical Center, presented the Studio topic: Utilizing
Tiffany solicited advice from on how to develop and utilize electronic consents effectively and compliantly.

- **Increasing Recruitment and Retention in Adolescent Menstrual Pain Study**  
  *Presented May 13, 2020*

Dr. Frank Tu of NorthShore University HealthSystem introduced the Studio topic: Increasing Recruitment and Retention in Adolescent Menstrual Pain Study. The goal of the study is to predict which girls develop more painful periods and to learn how a girl’s first experience of her period impacts the evolution of overall pain sensitivity at bladder and muscular sites.

Dr. Tu and his team were looking for new strategies in recruitment, recruitment of minorities, and retention of research subjects.

- **COVID-19 and Challenges in Continuing Research**  
  *Presented April 22, 2020*

Siqi Zhang, Honest Broker and Human-Centered Designer for Rush University Medical Center presented the Studio topic: COVID-19 and Challenges in Continuing Research. She presented various challenges that Rush-based study teams are facing while working remotely due to COVID-19, such as communication complications, protocol adaptations, and challenges with the transition to remote work.

Siqi opened up the discussion for ITM research teams to explore the issues they are all facing. She was looking to discuss potential opportunities for all Institute for Translational Medicine institutions to assist each other with COVID challenges.

- **How Do We Enable Study Teams to Use All the Available TRIO Resources?**  
  *Presented March 25, 2020*

Ashley Lopez, Honest Broker and Coordinator for the Trial Recruitment Innovation Office (TRIO) within the Institute of Translational Medicine (ITM), presented the Studio topic: How Do We Enable Study Teams to Use All the Available TRIO Resources? Ashley gave background information and introduced the goal of the office.

Ashley was looking to increase enrollment in research studies by engaging study teams with TRIO.

- **Prospective Studies in the Adult ICU**  
  *Presented March 11, 2020*

Anne Pohlman, RN, APN-CNS, FCCM of University of Chicago Medicine presented the Studio topic: Prospective Studies in the Adult ICU.

Anne introduced the struggles that she and her team face in the Medical Intensive Care Unit (MICU) involving the consenting process for prospective, minimal risk, research projects spanning from enrollment to follow up.

- **CAPriCORN: From Request Through Query to Results: How Can We Do Better?**  
  *Presented February 14, 2020*

Anthony Solominides PhD, MSc (Math), MSc (AI), FAMIA of NorthShore University HealthSystem introduced the Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN), a PCORI-funded Clinical Data Network, and presented their struggles with providing a responsive, accurate, and smooth research data request service to the research community.

Dr. Solominides was looking for help on how to translate a researcher’s request for data into an executable query against a common data model, and how to do this correctly and efficiently.

- **Increase Recruitment for Teen Night Owl Study**  
  *Presented January 8, 2020*

Logan G. Killen, Research Coordinator working under the Principal Investigator Stephanie Crowley, PhD, introduced the Studio Topic, How to Improve Recruitment Strategies for a Dual-Site Sleep and Circadian Rhythms Study of Adolescents Aged 14 to 17 Years. The research team sought out guidance on how to increase enrollment in their research study.

- **Wearable Devices Used for Detecting and Forecasting Health Events**  
  *Presented December 13, 2019*

Andrey Rzhetsky, Professor of Medicine, Department of Computational Biomedicine and Biomedical Data Science at the University of Chicago, introduced the Studio topic, Wearable Devices Used for Detecting and Forecasting Health Events. Dr. Rzhetsky was invited to submit a grant to the American Heart Association and was looking for guidance on enrolling subjects in his potential study.

- **The Cyclotron Facility and PET Imaging**  
  *Presented November 13, 2019*

Chin-tu Chen, PhD from the University of Chicago, Department of Radiology, gave background information and introduced the Cyclotron Facility and PET Imaging services. Dr. Chen presented the facility, sharing information on how it works and what they envision for its future.

As the only academic cyclotron-based radiotracer production facility within Illinois, Dr. Chen was looking to increase the number of users on-site and from other universities in the surrounding areas.

- **Future of the CTSA Program**  
  *Presented October 23, 2019*

Gerald Moose Stacy, Administrative Director of the Institute for Translational Medicine (ITM) introduced the Studio topic: the Future of the
CTSA Program. The Current FOA expires on 2022. The CTSA reached out to see how the program might be strengthened to deliver on its promise to develop, demonstrate and disseminate innovative approaches, methodologies and interventions that translate into improved human health.

- **How to engage student champions in research?**
  Presented October 9, 2019
  David Sedillo and Amelia Williams, Rush University Medical Center, introduced their TRIO Studio on how to engage student champions in research. David and Amelia explained their goal is to develop a system that will allow student champions to engage in research opportunities and advance recruitment efforts.

- **Can we use data-driven strategies to address urgent clinical and public health needs for individuals with substance misuse?**
  Presented September 25, 2019
  Majid Afshar, M.D., M.S., Loyola University Chicago, introduced his R01 grant he will be submitting in February of 2020. He is looking for feedback on how he can use data-driven strategies to address urgent clinical and public health needs for individuals with substance misuse across several ITM Institutions and the City of Chicago. Majid requested the studio audience to ideate solutions on building a learning health care system that will harmonize data across hospitals, fire and police data systems to accurately identify substance misuse, capture important risk factors, and prioritize patients that are at highest risk for poor health outcomes.

- **Increase Recruitment and Retention in Behavioral 3 Chronotype: Impact on Sleep and Metabolism Study**
  Presented September 11, 2019
  Stephanie Sinetas and Wajdey Neshweiwat, Research Coordinators at the University of Chicago, introduced the study and the problem to the studio participants. Stephanie and Wajdey are looking to increase recruitment and retention of research subjects in their study.

- **Coping and Managing End of Life for Clinical Trial Participants**
  Presented August 28, 2019
  Lauren Wall, Elaine Hoekstra, Morgan Whipkey, and Aurelie Desgardin from the University of Chicago (UChicago) are looking to educate and develop standard processes for clinical research staff on how to handle clinical trial patients who enter hospice/end of life.

- **Magnetic Resonance Imaging Center Underutilized at UChicago**
  Presented August 14, 2019
  Greg Karczmar, Ph.D. University of Chicago, was looking to increase participation at the MRIRC by engaging study teams with their current resources.

- **Enable Study Teams to Use All The Available TRIO Resources**
  Presented July 24, 2019
  Drew Simon, Rush University Medical Center (RUMC) was looking to increase enrollment in research studies by engaging study teams with TRIO resources.

- **All ITM Institutions Alerting Their Patients About Studies Not Done at Their Institution**
  Presented July 10, 2019
  Drew Simon, Rush University Medical Center (RUMC) was looking to increase enrollment in research studies done at all ITM institutions by advising patients about studies done at Rush and at other ITM institutions. Her role is described as an Honest Broker at Rush.

- **Recruitment and Retention for the PrecISE Asthma Trial**
  Presented May 8, 2019
  Steve White, M.D., University of Chicago, introduced the PreCISE severe asthma study to be conducted at University of Chicago, Northwestern Memorial Hospital and University of Illinois at Chicago. He gave background information and introduced the perceived recruitment challenges to the studio audience.

- **Recruitment and Successful Intervention in the US Pointer Chicagoland Site**
  Presented April 15, 2019
  Martha Clare Morris, Sc.D., Rush University Medical Center, introduced the US POINTER clinical trial to be conducted in the Chicagoland region by Rush and Advocate-Aurora sites. She gave background information and introduced the perceived recruitment challenges to the studio.

- **DBS Outcomes in Parkinson's Disease**
  Presented March 13, 2019
  Gian Pal, M.D., M.S., of Rush University Medical Center, introduced his study which is currently funded on a K award. His goal is to predict outcomes after deep brain stimulation for Parkinson’s Disease (PD). He is currently writing an R01 and requests feedback on his aims and which direction to go for his R01, in particular, from a goal of enhancing potential participant recruitment and retention.

- **Recruitment for Promoting Healthy Lifestyles Study**
  Presented February 13, 2019
  Patrick Corrigan, Ph.D., of Illinois Institute of Technology introduced his study as a single-center, three-arm, randomized controlled trial. Subjects who will be asked to participate will be African American with serious mental illness and obesity with a BMI of 30 or
over. They also want to lose weight. Dr. Corrigan and his team are currently in year two of recruitment and plan to enroll 30 subjects by March 4th, 60 by early April and 90 by early May. Dr. Corrigan requested the studio audience to ideate solutions on recruitment problems.

- **Increasing Clinical Research Follow-up Survey Rates with an Elderly Population**  
  Presented January 9, 2019

Mary Harris and Laura Magda, Section of Hospital Medicine, introduced the Comprehensive Care, Community, and Culture (C4P) Program at the University of Chicago. Subjects who will be asked to participate follow-up phone calls every three months. Mary and Laura requested the studio audience to ideate solutions for three questions:

1. How do they increase timely patient participation in follow-up surveys over long periods of time?
2. How do they decrease survey refusals, particularly in the non-intervention group?
3. How do they better understand the barriers surrounding participation of vulnerable populations in longitudinal research?

- **Recruitment and Study Design for Kidney Transplantation Microbiome Study**  
  Presented November 28, 2018

Pratik Shah, M.D., Section of Nephrology, University of Chicago Medicine, introduced his study as a single-center, prospective, observational cohort study. Subjects who will be asked to participate in the study are adult kidney transplant recipients with no diagnosis of irritable bowel disease or on probiotics. Dr. Shah and his team plan to enroll 40 subjects on the study in a year. Dr. Shah requested the studio audience to ideate solutions for two questions:

1. How do we get pre-transplant time-matched stool samples from our subjects?
2. How do we recruit from other ITM institutions for this study?

- **Opportunities for Collaboration between Researchers and Informaticians**  
  Presented November 14, 2018

Tony Solomnides, NorthShore University Health Systems, defined informatics as the the interdisciplinary field that studies and pursues the effective uses of biomedical data, information, and knowledge for scientific inquiry, problem solving and decision making, motivated by efforts to improve human health. He gave background information on informatics from all 6 ITM institutions and introduced the subsequent challenges of collaboration between researchers and informatics research services which should occur early in the research question formation process to the studio.

- **Study on the Role of Inflammation in Progressive Multifocal Leukoencephalopathy (PML)**  
  Presented October 24, 2018

Igor Koralnik, M.D., Neuroinfectious Diseases, Rush University Medical Center, introduced Progressive Multifocal Leukoencephalopathy (PML) and the subsequent challenges of enrolling eligible PML subjects at Rush University Medical Center and John H. Stroger, Jr. Hospital of Cook County. Dr. Koralnik gave background information on his study personnel which includes three physicians all at Rush and two who also practice at Stroger. He also has two clinical coordinators in his team. He gave background information on PML which is often a deadly disease of the brain for which there is no cure. It is caused by the reactivation of JC virus, which infects most of the healthy population without causing any disease. If patients are on immunosuppresants, JC virus can destroy brain cells, leading to multifocal demyelination and PML.

The primary aims of the study are to determine the role of inflammation in PML, characterize T cell response against JC virus, define MRI markers of outcome and understand why PML patients develop seizures. Procedures for the study include an office visit at 3, 6 and 12 months which are billed to insurance. Blood samples are drawn to measure cellular immune response to JC virus, a dense array EEG is done, and an MRI at UIC MRI Core Center also is performed. These are all billed to the study.

Dr. Koralnik requested studio audience to ideate solutions for two questions:

1. How to improve recruitment and communication with potential study subjects?
2. How do we improve the number of referrals for this study from across Chicagoland?

- **Facilitating Engagement Across Disciplines, in Complex, Multi-Disciplinary Study**  
  Presented October 10, 2018

Lindsay Basto, University of Chicago, introduced the transplant study and facilitating engagement across disciplines in this complex multi-disciplinary study and the challenges her team is experiencing. She gave background information and introduced the challenges to the studio.

- **How do we Establish a Process to Complete Feasibility Assessments for Studies at Initial Contact and throughout the Life Cycle of Project?**  
  Presented September 12, 2018

Jessica E. Shore, Loyola University, introduced the process of feasibility assessments for studies at initial contact and throughout life cycle of project. She described how Clinical Research Office (CRO) should ideally be engaged at the beginning of the research project during the proposal stage, when CDA/Site feasibility is not yet complete with industry sponsor. But, this much needed early feasibility assessment does not always occur, especially at the initial contact stage of the project proposal. Jessica asked the studio to focus on ideas that help address the feasibility issues at the initial stage of contact rather than mid-cycle or even later.
• How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?
  Presented August 8, 2018

  Sherry Robison, University of Chicago Institute for Translational Medicine, introduced the Trial Innovation Network (TIN) requests for quantitative data from ITM and the subsequent challenges of obtaining the data from ITM’s six member institutions. She gave background information on ITM, CTSAs and TIN including TIC (Trial Innovation Center) and RIC (Recruitment Innovation Center) and introduced the challenges of communication and informatics to the studio.

• Study Approval Timeline: Too Many Moving Parts
  Presented June 13, 2018

  Rachel Pulido, NorthShore University Health System, introduced the study approval process and the challenges of study start up. She gave background information and introduced the challenges to the studio.

• Recruitment for the Myocardial Ischemia and Transfusion Study
  Presented May 9, 2018

  Kirsten Hendrickson, Rush University Medical Center (RUMC), introduced the goal of the MINT Study and the challenges of enrolling participants. She gave background information and introduced the challenges to the studio on how to best recruit for this study. MINT study aims to determine whether a liberal transfusion strategy with a threshold of 10 g/dL reduces the 30-day composite outcome of all-cause mortality or nonfatal myocardial reinfarction compared to a restrictive transfusion strategy with a threshold of 7 to 8 g/dL among 3,500 patients with an acute myocardial infarction and a hemoglobin concentration less than 10 g/dL.

• Engaging Clinical Ambassadors for the All of Us Research Program
  Presented April 11, 2018

  David Sedillo, Rush University Medical Center (RUMC), introduced the goal of the All of Us Research Program and the challenge of creating an infrastructure wherein the many clinicians in our health systems can be advocates for their patients’ participation in the study.

  He gave background information and introduced the challenges to the studio on how to best create and maintain interest of clinicians and encourage enrollment of their patients in the All of Us Research Program. Patients want and need support from their clinicians to participate, but clinicians are overwhelmed with various messages. So, how do we get busy clinicians engaged?

Recruiting Studies
  • Sleep & Food Study
  • Asthma Study
  • Insomnia Study
  • Chronic Pelvic and/or Bladder Pain
  • Girls Ages 10-13 to Study Women’s Health
  • Women’s Health Painful Periods

Trial Innovation Network Responses
  HEAL Requests

HEAL Requests