TRIO Studio Presentations and Report

- **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. He was invited to submit a grant to the American Heart Association and was looking for guidance from a TRIO Studio for enrolling human subjects in to 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 is 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 to 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.

  Martha Clare Morris, Sc.D. and Darren Gitelman, M.D. are looking for suggestions for improving the recruitment and retention strategy in the US POINTER study.

- **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, 2019

  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 Solomonides, NorthShore University Health Systems, defined informatics as 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 immunosuppressants, 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 multidisciplinary 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 infarction 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
- Healthy Lifestyles

**Trial Innovation Network Responses**

**HEAL Requests**

HEAL Requests