ITM Trial Recruitment Innovation Office

TRIO Studio Presentations and Reports

- Recruitment and Successful Intervention in the US POINTER Chicagoland Site
  Presented 4/15/2019

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 3/13/2019

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 2/13/2019

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 1/9/2019

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?

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

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.

- Opportunities for Collaboration between Researchers and Informaticians
  Presented 11/14/2018

Tony Solomonides, 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 institions 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 10/24/2018

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?

- **Recruitment and Study Design for Kidney Transplantation Microbiome Study**
  Presented 11/28/2018

  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?

- **How Do We Effectively Respond to the Trial Innovation Network (TIN) Requests?**
  Presented 8/8/2018

  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.

- **Engaging Clinical Ambassadors for the All of Us Research Program**
  Presented 4/11/2018

  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?

- **Recruitment for the Myocardial Ischemia and Transfusion Study**
  Presented 5/9/2018

  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.

- **Study Approval Timeline: Too Many Moving Parts**
  Presented 6/13/2018

  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.

- **How do we Establish a Process to Complete Feasibility Assessments for Studies at Initial Contact and throughout the Life Cycle of Project?**
  Presented 9/12/2018

  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.