

“Everything you wanted to know about Geriatric clinical trials and were afraid to ask.”
How to Conduct Clinical Trials in Geriatric Psychiatry

This course will provide practical overview and guide to conducting clinical trials in geriatric psychiatry. Presenters will discuss specific operational elements of setting up clinical trials practice(s), resources needed to conduct clinical trials in this population, interaction and decision-making process dealing with sponsors including contract and financial considerations, oversight, staff selection, training and regulatory and good clinical practice requirements. Finally, a panel of thought leaders will discuss the applicable specific areas of research and challenges associated with conducting trials in each area. The course will be divided into two sessions with a total of seven presentations that will take place on the same day. The morning session will include three presentations, which will provide information on the types and current resources and structure of operations that are needed at a potential study site to be able to participate in any of the prospective clinical trials. This includes staffing, training, physical resources, policies and procedures, and other resources that need to be in place for a clinical trial to be successfully conducted at a given site. The specific needs that will should be in place for a given site to be able to participate in upcoming trials, and how the sites can transition from a clinical site to a research site and from a research site of today to a research site of tomorrow will be discussed. Finally, presentations on how to evaluate potential protocol to determine whether the protocol is appropriate for your practice, will be discussed.

During the afternoon session, four presentations will provide practical information on the operational aspects of conducting a clinical geriatric trial from regulatory requirements, recruitment strategies and financial aspects of running a profitable and successful practice. Last presentation will include a panel of experts who will review and discuss current clinical trials being conducted in the field of geriatric mental health and the challenges associated with conducting trials in each research area.

Faculty/Presenters: Mary Sano, PhD, Icahn School of Medicine at Mount Sinai, Olga Brawman Mintzer, MD, Medical University of South Carolina, Joan Mackell, PhD, JM Neuroscience, LLC, and Lon S. Schneider MD, Keck School of Medicine of USC

AGENDA

9:30 – 10:00 Presentation 1: Clinical Trial Practice Models: Advantages and Risks to Consider

Summary: Conducting clinical trials can be a fulfilling and profitable aspect of medical service delivery. Whether creating your own practice or participating in an existing one, understanding the business and service models in which clinical trials are conducted is important variable for success. This session will explore the strategic and business aspects of several of these models in academic, private and commercial practices. The interplay between clinical and research activities, the support, services, responsibilities, assets and liabilities within each model will be discussed. The goal will be to identify features for success in clinical trials focused on geriatric psychiatry within these models.

10:00 – 10:45 Presentation 2: Building the team to do research within a clinical practice
Mary Sano

Summary: Clinical trials are a “team sport” and there are several expected positions and roles common to any clinical trial enterprise. Additionally, trials there are unique needs, in geriatric psychiatry trials, which can increase the number of particular individuals, with specific knowledge and experience who are required in order to conduct a given trial. These may include individuals with experience in cognitive

or behavioral ratings, knowledge of how to recruit for aging populations, and those with competence and expertise in specialized procedures. Finding, training and retaining this work force can be challenging. Creating ties with teaching and training programs as well as with professional societies can support your workforce and help to build a cohesive team. This session will discuss how to identify and keep the right type of staff for these studies.

10:45 – 11:15 Presentation 3: “Is this protocol right for me”
Olga Brawman-Mintzer

Summary: During the third presentation we will offer guidelines for reading a protocol or synopsis to determine whether a particular trial is a good fit for your practice. Evaluating entry criteria to determine if they match with your practice or community, determining the work load and resource in terms of number and types of personnel required, space to conduct the study, as well as the length of the visits and the trial are key factors to selecting the best studies for your practice. Special attention will be paid to common features in trials for dementia, geriatric depression, and agitation and in trials with non-pharmacological elements. We will present sample “site-interest surveys” and considerations for completing them.

11:30 – 12:00 Presentation 4: Regulatory Knowledge
Joan Mackell

Summary: The fourth presentation will decipher regulatory guidelines and requirements. We will first focus on the regulatory information pertinent to the performance and obligations of the Principal Investigator. This will include the understanding of the Code of Federal Regulations (CFR) Title 21; how to comply with Good Clinical Practice (GCP); working with Institutional Review Boards (IRB), including forms to know, Informed consent form (ICF) and consenting process. We will also discuss delegation of roles in these activities.

1:00 – 1:30 Presentation 4: Regulatory Knowledge – Part Two
Joan Mackell

Summary: The second part of the regulatory session will focus on the pertinent information for sites’ regulatory staff from initial stages of site selection questionnaires, site selection visit to IRB submissions, protocol amendments, sponsor monitoring, and annual reviews throughout the study.

1:30 -2:15: Presentation 5: How to recruit subjects
Mary Sano

Summary: The major barrier to efficient completion of all clinical trials is recruitment and geriatric psychiatry is no different. While investigators often use clinical practice experience to determine the number of individuals they have available for enrollment, these impressions are seldom sufficient to accurately determine recruitment capacity. We will discuss how to assess the true number needed to meet recruitment goals for studies in geriatric conditions. Successful recruitment requires multiple sources of potential participants. We will provide practical ways to identifying sources and ways to build lasting bonds that are critical to engaging the aging community. Providing information important to

your target audience can create awareness of your practice, your mission and your team. These are critical elements to successful recruitment.

2:15 – 3:00 Presentation 6: Financial aspects: How will I pay the bills?
Olga Brawman-Mintzer

Summary: A critical issue facing investigators is how to approach and successfully manage the financial aspects of conducting clinical trials. Navigating contract and budget negotiations, and evaluating the financial risks involved can be complicated. In this session, we will attempt to demystify the financial aspects of clinical trials, and discuss how to analyze clinical trial agreements and budgets. This includes contract interpretation from indemnification, payment schedule, and screen failure reimbursement to contract termination. As a part of budgetary assessment, we will discuss and provide practical approaches to determine the true cost of procedures, assessing hidden costs and hidden savings in study procedures, recruitment and compliance (including creating budget/procedure templates), and how to negotiate with sponsors and vendors. Billing and billing oversight as well as payment tracking will be discussed. Understanding the financial components of a clinical trial allows for a successful interaction with sponsors, vendors and importantly, maintaining a sound fiscal enterprise.

3:15 – 4:00 Presentation 7: Panel Discussion: Topics in Geriatric Trials
Mary Sano; Olga Brawman Mintzer; Joan Mackell; Lon Schneider

Summary: During this final session, an esteemed panel of experts will discuss their insights and experience in dementia trials, geriatric depression, agitation and other behavioral disturbances. Each expert will provide an introductory brief overview on additional, relevant aspects of conducting these types of trials. The session is planned as a question and answer format allowing the audience to get feedback on the topics we discussed during the day.