New York State Chapter Fall Program
Friday, October 30, 2015
8:00-8:15 Sign-In; 8:15 - 3:30 Program
Location: SUNY Upstate Medical University, Weiskotten Hall, 766 Irving Ave., Room 2231 (Auditorium), Syracuse, NY 13210

8:00 – 8:15 Sign-In

8:15 – 8:25 Welcome and Introduction: Kathi Durdon, MA, CCRP, SoCRA NYS Chapter Chair, Director of Operations, CNYBAC

8:25 – 9:25 The SUNY Network Aging Partnership: Tales from the Front Lines of Clinical Research
Sharon A. Brangman, MD, FACP, AGSF, Distinguished Service Professor of Medicine, Division Chief of Geriatrics, SUNY Upstate Medical University
Abstract: The SUNY Network Aging Partnership (SNAP) is a group of geriatrics healthcare professionals representing the four SUNY academic health centers. We formed a research consortium and shortly received funding after submitting our first grant application. It turned out that getting funded was the easy part. This session will review some of the lessons learned when conducting clinical research on frail elders across the SUNY system.

9:25 – 10:25 FDA Inspections
Lisa A. Ware, MS, RAC, Director, Regulatory Affairs, Center for Global Health and Translational Science, SUNY Upstate Medical University
Abstract: FDA audits are something we all hope never happen. Proper preparation and conduct during and after an audit can affect the outcome. This session will present what the FDA will look for during an audit and lessons learned from an audit we experienced.

10:25 – 11:25 Quality System Approach to the Conduct of Clinical Trials
Glenda Guest, BS, CCRA, RQAP-GCP, TIACR, Vice President, Norwich Clinical Research Associates, Ltd.
Abstract: Regulatory agencies are sending a strong message that they expect to see quality systems built into clinical research activities. A high level overview of a Quality System approach to the conduct of clinical trials will provide the foundation for a more in depth discussion of specific activities that sponsors and sites can implement to improve quality outcomes. The concepts of quality control versus quality assurance, protocol optimization and data mapping will be presented and a group discussion will follow.

11:30 – 12:45 Topic-based Network Lunch (List of Dining Options attached)
Teams (4-5 members) will select topic from list to discuss during lunch, select a spokesperson, and have 5 minutes to report on their main discussion points. Team Reports will be held at the final session of the day; those interested may pursue potential article(s) for SoCRA Source or poster presentation abstract for 2016 Annual Conference (Montreal, Sept 30 – October 2).

12:45 – 1:45 Refresher on Statistical Terminology, Data Summary, and Statistical Inference – Part IV
Thomas T. John, Ph.D., Adjunct Faculty - Department of Mathematics Consultant – Statistics & Business Intelligence, Syracuse University
Abstract: This presentation will continue the review provided in Parts I through III as a refresher on statistical Terminology and statistical inference topics from the clinical research perspective. This time we will review sensitivity (true positive rate) and specificity (true negative rate). Some of the contexts where
sensitivity and specificity appear, as well as related topics (positive/negative predicted values, confusion matrix, and ROC curve) will also be reviewed.

1:45 – 2:45  
**Breaking the Communication Barrier: forming a Clinical Research Professionals Group at your Institution**  
Dena Martin, CCRP, Clinical Research Coordinator and Joanne Chilton, CCRP, Clinical Research Coordinator, Dept. of Radiation Oncology, Upstate Medical Univ, Co-Chairs, Clinical Research Professionals Group

Abstract: The intended purpose of the Professional Committee is to form a cohesive group among the Clinical Research Professionals (CRPs) in all departments of our institution. The importance of good, open communication between the CRPs and all areas that they interact with cannot be stressed enough. The most important aspect of this entire project has been the understanding that professionalism and respect must be given to be received.

2:45 – 3:30  
**Team Reports on Network Lunch Topics**  
**Discussion of potential poster(s)/article(s) for SoCRA**

SoCRA Members may be credited for (up to) (approval in process) hours Continuing Education Credit Hours. Each participant should claim only those hours of credit that he/she actually spent in the educational activity. Only SoCRA members will receive SoCRA certificates of attendance.

There is no registration fee for this program – anyone may attend – you do not need to be a SoCRA member. There will not be any food or drink provided for the program. Lunch will be on your own – there are plenty of dining areas in the neighborhood (see suggestions). Please feel free to bring your own beverages, lunch and/or snacks.

Program Contact: Kathi Durdon, 315-464-9290, durdonk@upstate.edu

**Network Lunch Topics:**
1. What are successful approaches to recruit and retain study participants?
2. What are your biggest barriers in your ability to conduct of clinical research?
3. What do you need to get to the next level in your career? What resources are needed?
4. What Quality Systems have you put in place to improve quality outcomes?
5. Do you have an SOP for FDA Inspection preparedness? Have you been inspected, if so, what did FDA look for/were you ready?
6. Are you a member of a Clinical Research Group within your Organization? What are the benefits? Do you think you may develop an organization if you don’t already have one and why?
7. What do you see for the future of clinical research in the US? Is the quantity of studies declining or increasing? Are the designs of studies changing? What are the hot topic issues?
8. Topic of team choice

**Parking:**
There are two parking garages on Irving Ave close to Weiskotten Hall: Crouse Irving Memorial Hospital Garage ($11.00 all day rate, 701 Irving Ave.). CNY Medical Center Garage ($14.00 all day rate, 710 S. Crouse Ave., entrance also on Irving Ave.). There are additional parking areas farther from the facility at a less costly rate. There is metered parking on the street but are set at a maximum of 2-hours, you would need to replenish the meter every 2 hours.

**Dining Choices “On the Hill”:**
- Varsity (pizza, salads, grill)
- Appethaizing (Thai)
- Samrat Indian Restaurant (Indian)
- Strong Hearts Café (Healthy, Salads)
- Starbucks (Coffee)
- Dunkin Donuts (Coffee, Doughnuts)
- Chipotle Mexican Grill (Mexican)
- Faegans Restaurant (salads, soups, sandwiches)
- Jimmy Johns Gourmet Sandwiches (subs, sandwiches)
- Pita Pita (Greek, Mediterranean, Middle Eastern)
- King David’s Restaurant (Greek, Middle Eastern)
- Panda West Chinese Restaurant (Chinese, Seafood)
- Bruegger’s Bagels (coffee, bagels, sandwiches)
- Insomnia Cookies (Yumm)