ADVANCED SITE MANAGEMENT: FINANCE AND PRODUCTIVITY WORKSHOP AGENDA

DAY ONE:

8:15 - 8:45 - Registration and Continental Breakfast

8:45 - 9:15 - Overview of Conference and Clinical Research Industry
Jim Simmer, BSN, MBA, President, Research Answers
Mr. Simmer will discuss the theme and overall goal of the conference as well as the state of the clinical research industry. Topics will include growth of the clinical research industry, economic pressures between sites and sponsors, and discussion of new research opportunities for advanced sites.

9:15 - 10:00 - Research Site Business Foundation
Jim Simmer, BSN, MBA, President, Research Answers
Mr. Simmer will lead a discussion that covers the foundational principles required to build a profitable research site. This lecture will address the structure of profitable sites, study pipelines, subject recruitment, and site productivity measurements.

10:00 - 10:15 - Break

10:15 - 11:15 - Research Site Business Foundation, Continued

11:15 - 12:00 - Clinical Research Billing Compliance
Andrew Snyder, MBA, FACMPE, PMP, Director, Clinical Trials Office, HealthEast Care System
Mr. Snyder will conduct a review of many significant concerns related to managing the billing compliance of research studies. This presentation will include a review of the relevant CMS billing regulations for clinical billing services in research studies. This lecture will also provide participants with tools to assist in making the right decisions and implementing billing systems for research programs.

12:00 - 1:00 - Lunch (Provided)

1:00 - 1:45 - Clinical Trial Budget Development
Andrew Snyder, MBA, FACMPE, PMP, Director, Clinical Trials Office, HealthEast Care System
Mr. Snyder will explain the systems used by sponsors to develop study budgets and the methods used by sites to assess these financial proposals. This lecture will explain the reasons sponsors and sites experience frequent conflict related to budget issues and provide techniques for managing the process.

1:45 - 2:30 - Clinical Trial Budget Analysis and Negotiation
Andrew Snyder, MBA, FACMPE, PMP, Director, Clinical Trials Office, HealthEast Care System
Mr. Snyder will cover the art and science of negotiating with sponsors for a budget that meets your needs and your sponsor’s as well.

2:30 - 2:45 - Break

2:45 - 3:15 - Study Selection
Beth Jorgenson, RN, BSN, MBA, CCRC, Program Manager, Clinical Trials Office, HealthEast Care System
Ms. Jorgenson will present concepts for you consider during the study selection process. Topics to consider during site selection include an examination of your successfully recruited trials, current state of business at your site, searching for new partnerships in your local vicinity, and networking to share study leads.

3:15 - 4:15 - New Staff and Career ladders-how these are related
Beth Jorgenson, RN, BSN, MBA, CCRC, Program Manager, Clinical Trials Office, HealthEast Care System
Ms. Jorgenson will discuss topics to consider for on-boarding, or training, new team members. She will also discuss the concepts associated with career ladders.

4:15 - 4:45 - Question & Answer Session/ Discussion
DAY TWO:

8:30 - 9:00 - Continental Breakfast

9:00 - 10:00 - Clinical Research Revenue Recognition
Andrew Snyder, MBA, FACMPE, PMP, Director, Clinical Trials Office, HealthEast Care System
Mr. Snyder will begin the presentation with a review of the types of research revenue. This presentation will include a demonstration of revenue recognition models and tools.

10:00 - 10:15 - Break

10:15 - 11:30 - Team Workload Management
Beth Jorgenson, RN, BSN, MBA, CCRC, Program Manager, Clinical Trials Office, HealthEast Care System
Ms. Jorgenson will discuss tools to objectively assess workload, review techniques to explore workloads with staff, and cover options to consider to level load your team’s capacities.

11:30 - 12:15 - Research Expense Management
Jim Simmer, BSN, MBA, President, Research Answers
Mr. Simmer will illustrate the challenges faced in managing expenses at a clinical research site. This presentation will include methods of defining research expenses, tracking research costs and controlling total expenses.

12:15 - 1:00 - Lunch (Provided)

1:00 - 2:00 - Research Program Profitability
Andrew Snyder, MBA, FACMPE, PMP, Director, Clinical Trials Office, HealthEast Care System
Mr. Snyder will demonstrate methods of calculating the profitability of a clinical research program in various organizations. This lecture will include a review of research specific profit and loss reporting and profitability forecasting for your research team.

2:00 - 2:45 Electronic documentation - maximizing your EMR
Beth Jorgenson, RN, BSN, MBA, CCRC, Program Manager, Clinical Trials Office, HealthEast Care System
Ms. Jorgenson will present ideas to maximize the electronic health record at your site. Using your EHR to document your research data provides security, traceability, and many times, ease of use for your investigators to maintain oversight of the clinical trial.

2:45 - 3:00 Break

3:00 - 3:45 FDA inspections - Lessons Learned
Beth Jorgenson, RN, BSN, MBA, CCRC, Program Manager, Clinical Trials Office, HealthEast Care System
Ms. Jorgenson will share lessons learned from two FDA inspections-1 device trial inspection and 1 pharmaceutical trial inspection. You will be able to list two processes that should be evaluated at your site prior to the inspector’s phone call.

3:45 - 4:15 Improving Physician Involvement
Jim Simmer, BSN, MBA, President, Research Answers
Mr. Simmer will discuss the challenges faced with improvement of physician involvement in research. He will offer strategies on how to efficiently increase physician oversight without being burdensome.

4:15 - 4:30 Question & Answer Session/ Discussion