

SOCRA Advanced Site Management: Finance and Productivity Enhanced Business Practices for Clinical Research Programs

DAY ONE

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

8:45 - 9:15 **Introductions and Orientation**

Jim Simmer, BSN, MBA, President, Research Answers

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

Mr. Simmer and Mr. Snyder will discuss the essence of financial and productivity issues involved in site management.

9:15 - 10:00 **Clinical Research Industry - Why Can't We Just Get Along?**

Jim Simmer, BSN, MBA, President, Research Answers

Mr. Simmer will discuss the state of the clinical research industry. Topics include growth of the clinical research industry, economic pressures between research sites and sponsors, and a discussion of new research opportunities for advanced sites.

10:00 - 10:15 **Break**

10:15 - 11:45 **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.

11:45 - 12:45 **Lunch (Provided)**

12:45 - 1:30 **Clinical Research Billing Compliance**

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

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.

1:30 - 1:45 **Interactive Demonstration - Conduct a Billing Analysis**

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

Mr. Snyder will request the assistance of an attendee volunteer and conduct a **billing analysis** on a research protocol. This session will conclude with each participant taking home a customized billing tool.

1:45 - 2:30 **Clinical Trial Budget Development**

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

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.

2:30 - 2:45 **Break**

2:45 - 3:30 **Clinical Trial Budget Analysis and Negotiation**

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

This presentation will include detailed instructions for reviewing and negotiating a study budget. This lecture will include a demonstration of tools that can be used to develop a clear and transparent budget analysis.

3:30 - 4:00 **Interactive Demonstration - Conduct a Budget Analysis**

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

Mr. Snyder will request the assistance of an attendee volunteer to complete a **cost analysis** on a research protocol in order to introduce an additional perspective. This session will conclude with each participant taking home a customized budget analysis.

4:00 - 4:15 **Role Playing - Negotiate a Clinical Trial Budget**

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

Jim Simmer, BSN, MBA, President, Research Answers

The instructors and participants will role play the processes involved in negotiating a clinical research budget.

4:15 - 4:45 **Question & Answer Session/ Discussion**

DAY TWO

8:30-9:00

Continental Breakfast

9:00-9:30

Clinical Research Revenue Recognition

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

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.

9:30-10:45

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.

10:45-11:00

Break

11:00-11:30

Research Accounts Receivable Management

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

Mr. Snyder will provide a method of assessing your study performance and revenue position. This lecture will show participants how to manage their research program accounts receivable and business office reporting requirements.

11:30-12:00

Research Collections

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

Mr. Snyder will demonstrate a detailed process for managing the research collections process and enhancing cash flow at the research site.

12:00-1:00

Lunch (Provided)

1:00-1:15

Clinical Research Current Events and Hot Topics

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

Mr. Snyder will discuss current events and hot topics that are impacting clinical research finance and budgeting. This discussion will focus on Subject inquiry and the Sunshine Act.

1:15-2:00

Impact of Risk Based Monitoring from the Site Perspective

Jim Simmer, BSN, MBA, President, Research Answers

Mr. Simmer will explain the practice of Risk Based Monitoring and how it will impact the clinical research site. He will examine the rationale for the change in traditional monitoring approach. Then offer solutions to not only mitigate the impact but to improve site performance in this new environment.

2:00-3:00

Research Program Profitability

Andrew Snyder, MBA, FACMPE, PMP, Director of Operations and Research, HealthEast HeartCare

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.

3:00-3:15

Break

3:15-3:45

Interactive Demonstration - Conduct a Research Site Pro Forma

Mr. Snyder will present a real-world scenario in which a site professional must forecast a research site's financial results in the future. Mr. Snyder will demonstrate an easy-to-use system for completing a detailed and accurate research program pro forma.

3:45-4:00

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.

4:00-4:30

Question & Answer Session/ Discussion