

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, MBA, RN, Principal, Performance Research Consulting
Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, 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, MBA, RN, Principal, Performance Research Consulting
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, MBA, RN, Principal, Performance Research Consulting
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, 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 implementation systems for research programs.
- 1:30 - 1:45 **Interactive Demonstration - Conduct a Billing Analysis**
Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, 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, 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, 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, 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 <i>Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, HealthEast HeartCare</i> <i>Jim Simmer, MBA, RN, Principal – Performance Research Consulting</i> The instructors and participants will role play the processes involved in negotiating a clinical research budget.
4:15 - 4:45	Question & Answer Session/ Discussion
<u>DAY TWO</u>	
8:30-9:00	Continental Breakfast
9:00-10:00	Clinical Research Revenue Recognition <i>Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, HealthEast HeartCare</i> 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.
10:00-10:45	Research Expense Management <i>Jim Simmer, MBA, RN, Principal, Performance Research Consulting</i> 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 <i>Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, HealthEast HeartCare</i> 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 <i>Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, HealthEast HeartCare</i> 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)
1:00-2:00	Research Program Profitability <i>Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, HealthEast HeartCare</i> 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.
2:00-2:30	Interactive Demonstration - Conduct a Research Site Pro-Forma <i>Andrew Snyder, MBA, FACMPE, PMP, Director of Operations, HealthEast HeartCare</i> 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.
2:30-2:45	Break
2:45-3:15	Microsoft Excel and Research Finance <i>Jim Simmer, MBA, RN, Principal, Performance Research Consulting</i> This module will compare and contrast Microsoft Excel software capabilities with generally available functionality available in a Clinical Trials Management System. Participants will learn how to use excel formulas to manage financial aspects of trials, to invoice sponsors, and to link spreadsheets to create reports.
3:15-4:00	Clinical Research Executive Management Reporting <i>Jim Simmer, MBA, RN, Principal, Performance Research Consulting</i> Mr. Simmer will describe the challenges faced with reporting the results of your research program to your institution's executive management. This lecture will illustrate various executive dashboard reporting metrics and assist participants in developing a monthly status report.
4:00-4:30	Question & Answer Session/ Discussion