

SoCRA Clinical Research Project/Program Management Conference

DAY ONE

8:00 - 8:30 **Registration and Continental Breakfast**

8:30 - 10:00 **Project Management - Developing an Infrastructure**

Daniel Redline, BA, CCRC, CCRP, Pre-Market Clinical Project Manager, Volcano Corporation

Nancy Wintering, MSW, LCSW, CCRP, Research Program Manager, Thomas Jefferson University

This session will review the processes and procedures necessary for developing an infrastructure to support the various tasks associated with Project Management. Such activities require selecting and developing the proper tools for success.

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

10:15 - 10:45 **Project Management - Developing an Infrastructure: Tools and Techniques**

Nancy Wintering, MSW, LCSW, CCRP, Research Program Manager, Thomas Jefferson University

Tools and techniques to be discussed include; development and implementation of Standard Operating Procedures, building and managing the cross-functional research team and organizing and managing the workplace.

10:45 - 11:30 **Project Management - Developing an Infrastructure: Charts, Planning and Communication Tools**

Daniel Redline, BA, CCRC, CCRP, Pre-Market Clinical Project Manager, Volcano Corporation

Staying on track is a key to success in project management. This session will focus on prioritizing and managing tasks, developing time/project management tools for planning and progress assessment.

11:30 - 12:15 **Project Management in Clinical Trials: Introduction to PMI Principles**

Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP, Senior Director Clinical Operations, UCSF Immune Tolerance Network

It has become increasingly more important to use solid project management principles when managing clinical trials. Dr. Sivaramakrishna will introduce participants to project management principles following PMI (Project Management Institute) guidelines (Initiation, Planning, Execution, Monitoring, Controlling, and Closing), as well as basic principles of risk management. Project management tools will be provided and discussed. Situational examples will be provided in order to maximize interaction and discussion.

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

1:00 - 2:30 **Project Management in Clinical Trials: Introduction to PMI Principles (Continued)**

Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP, Senior Director Clinical Operations, UCSF Immune Tolerance Network

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

2:45 - 4:00 **Project Management in Clinical Trials: Introduction to PMI Principles (Continued)**

Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP, Senior Director Clinical Operations, UCSF Immune Tolerance Network

4:00 - 5:00 **Organizational Dynamics in Project Management: Different Styles, Different Expectations**

Nancy Wintering, MSW, LCSW, CCRP, Research Program Manager, Thomas Jefferson University

Psychological issues may arise unexpectedly that have an impact on the activities and relationships in clinical trial management. This session is designed to build competencies to manage more effectively while working with different leadership and personality and organizational styles. Ms. Wintering will present strategies to manage stress, to recognize and resolve conflict proactively to promote effective team building.

DAY TWO

8:00-8:30 **Continental Breakfast**

8:30-10:00 **Creating a Study Budget and Managing Finances From Start Up to Close Out**

Jennifer Goldfarb, RN, CCRP, Manager & Head Research Nurse Coordinator, Department of Dermatology, University of Pennsylvania

Ms. Goldfarb will discuss budget development and financial management topics including: general start up issues, study feasibility and potential pitfalls in budgeting, including strategies to manage impasses and identify hidden costs. The session will address study tracking and site management throughout the course of the study. This will include illustrating the use of tools such as budget benchmarking and cost funds flow in budgetary planning and study execution. Ms. Goldfarb will also highlight the importance of accurate research billing including Billing to CMS (Centers for Medicare & Medicaid Services) and financial management throughout the study conduct, including patient status and payment tracking.

DAY TWO (continued)

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

10:15-11:15 **Contract Development for Good Outcomes for Site and Sponsor**

Lisa Benson, BS, CCRP, Director of Grants & Sponsored Programs, Department of Research, Connecticut Children's Medical Center

Ms. Benson will discuss contract development topics including: intellectual property (IP) rights, publication, indemnification and clinical trial sponsor interactions and negotiations. The session will also highlight the importance of accurate contract language relative to the protocol, monitoring plan and sponsor agreements.

11:15- 12:15 **Working With Pharmacies in Project Management**

John Petrich, MS, RPh, Investigational Drug Service Manager, Cleveland Clinic Foundation

Mr. Petrich will discuss pharmacy issues related to staff responsibilities, associated training and project planning considerations. The role of the pharmacist and the pharmacy is critical in the research design and implementation. Topics will include: drug accountability, randomization, inventory control. Participants will discuss the importance of risk management systems and safety.

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

1:00-2:00 **Developing Projects Related to INDs and IDEs**

Daniel Redline, BA, CCRC, CCRP, Pre-Market Clinical Project Manager, Volcano Corporation

Nancy Wintering, MSW, LCSW, CCRP, Research Program Manager, Thomas Jefferson University

The speakers will discuss requirements for Investigational New Drug (IND) and IDE Investigational Exemption (IDE). They will describe the various guidance documents and forms designated for use by industry and academic research sponsors and sponsor-investigators. Drugs and devices have distinctive FDA regulations which the speakers will compare and contrast. Topics include; the CFR, FDA guidance documents, study design requirements, protocol development and regulatory pathways. The importance of developing stakeholder relationships in project planning with Data Safety Monitoring Boards and compliance entities will be discussed.

2:00-3:00 **Global Regulatory Considerations Affecting the Project Plan**

Daniel Redline, BA, CCRC, CCRP, Pre-Market Clinical Project Manager, Volcano Corporation

International investigational sites typically follow International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. However, these guidelines do not address the processes/ requirements related to applications/submissions to local and national regulatory authorities. Topics will include the U.S. Code of Federal Regulations (CFR), ICH GCP and ISO standards (International Organization for Standardization), as well as discussion regarding the organization of the competent authorities/notified bodies of those countries.

3:00-3:15 **Break**

3:15-4:30 **Managing Multisite Projects, Planning for the Unexpected**

Angela Kimel, BS, MBA, CCRP, Research Associate, Epidemiology and Prevention, Wake Forest University Health Sciences

This session will focus on issues involved in managing multiple investigational sites. The interface among multiple IRBs, Clinical Investigators, sponsors and regulatory entities will be discussed. Strategies to be discussed will include; how to work in partnership with IRBs to expedite the review process and streamline multiple review entity approvals simultaneously, how to work effectively with compliance entities. Specific attention will be given to risk management and disaster planning in clinical research.

4:30- 5:00 **Question & Answer Session/ Discussion**