DAY ONE: THURSDAY

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

8:30 - 8:40 - Introduction to SOCRA

8:40 - 10:15 - Project Management - Developing an Infrastructure
Nancy Wintering, MSW, LCSW, CCRP, *Assistant Director of Research, Thomas Jefferson University, Marcus Institute of Integrative Medicine*
Daniel Redline, BA, CCRP, CIP, *Senior Director, Global Clinical Affairs, Align Technology*
This session will provide an overview of the project management processes: (Initiation, Planning, Execution, Monitoring, Controlling, and Closing) as well as strategic and operational planning. The speakers will review processes and procedures from both sponsor and site perspectives that are necessary to develop an infrastructure and to manage the cross-functional research team that supports the various tasks and stakeholder relationships associated with project management.

10:15 - 10:30 - Break

10:30 - 12:00 - Project Management in Clinical Trials: Introduction to PMI Principles
Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP, *Consultant*
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 Project Management Institute (PMI). A brief history of PMI, key terms, the project life cycle, and knowledge areas will be discussed.

12:00 - 12:45 - Lunch (Provided)

12:45–2:45 - Project Management Organization: Charts, Planning & Tracking, Tools & Techniques
Daniel Redline, BA, CCRP, CIP, *Senior Director, Global Clinical Affairs, Align Technology*
Nancy Wintering, MSW, LCSW, CCRP, *Assistant Director of Research, Thomas Jefferson University, Marcus Institute of Integrative Medicine*
Staying on track is a key to success in project management. This session will focus on developing and maintaining project management tools and techniques for project planning and assessment of progress. Gantt Charts, Standard Operating Procedures, file naming conventions, flowcharts, shared calendars to organize and manage the workplace will be discussed.

2:45–3:00 - Break

3:00–4:30 - Project Management in Clinical Trials: Project Management Knowledge Areas and Process Group Mapping
Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP, *Consultant*
Dr. Sivaramakrishna will introduce participants to project management principles following PMI (Project Management Institute) guidelines as well as project management knowledge areas and process group mapping. Project management tools will be provided and discussed. Situational examples will be provided in order to maximize interaction and discussion.

4:30–5:00 - Virtual Project Management
Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP, *Consultant*
More and more, clinical project management is done globally across multiple time zones and cultures. In order to be successful, certain adaptations have to be made to routine practices. Dr. Sivaramakrishna will discuss some of the challenges related to virtual project management and solutions for the same. Situational examples will be provided where applicable.

DAY TWO: FRIDAY

8:00–8:30 - Continental Breakfast

8:30–10:00 - Project Management in Clinical Trials: Risk Management and Risk Mitigation
Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP, *Consultant*
Dr. Sivaramakrishna will introduce basic principles of risk management, risk avoidance and risk mitigation. Project management tools will be provided and discussed. Situational examples will be provided in order to maximize interaction and discussion. Project management knowledge areas will be summarized.

10:00–10:15 - Break

10:15–11:45 - Creating a Study Budget and Managing Finances From Start Up to Close Out
Jennifer Goldfarb, MSN, RN, CCRP, *Vice President, Clinical Research Operations, The IMA Group*
Ms. Goldfarb will discuss budget development and fi nancial management topics including: general start up issues, study feasibility, potential pitfalls in budgeting, and 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 fl ow 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.

11:45–12:30 - Lunch (Provided)

12:30–2:15 - Contract Development for Good Outcomes for Site and Sponsor
Lisa Benson, BS, CCRP, *Vice President, Clinical Research Operations, Quality & Education,*
Institute of Advanced Clinical Trials for Children
Ms. Benson will discuss the contract review process and the importance of successful interactions between Sponsors, CROs and Sites when negotiating Clinical Trial Agreements. Ms. Benson will review key elements of a Clinical Trial Agreement and particularly focus on two key areas, Study Budgets and Payment Terms. Sponsors and Sites will have the opportunity to have open discussions with one another on the challenges that they face in regards to Study Budgets and Payment Terms to better understand one another's perspective. Other terms to be reviewed are Intellectual Property, Monitoring Visits, Audits and Subject Injury. Ms. Benson will provided examples of tracking tools and how they relate to
effective contract management.

2:15–2:45 - Planning for the Unexpected
Erich Lukas, MBA, *Executive Director, Society of Clinical Research Associates*
This session will consider various aspects of recovery planning. The environment, including natural and man-made disruptions and disasters, is full of scenarios to be considered by the project manager/planner. The discussion will include a view of current regulations and guidance regarding data management in view of the potential need for data, forms, and information recovery.

2:45–3:00 - Break

DAY TWO (CONTINUED) : FRIDAY

3:00–4:15 - Organizational Dynamics in Project Management: Different Styles, Different Expectations
Nancy Wintering, MSW, LCSW, CCRP, *Assistant Director of Research, Thomas Jefferson University, Marcus Institute of Integrative Medicine*
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 recognize and resolve conflict proactively and to promote effective team building.

4:15–5:00 - Managing Moves of Multiple Clinical and Research Programs
Lisa Benson, BS, CCRP, *Vice President, Clinical Research Operations, Quality & Education, Institute of Advanced Clinical Trials for Children*
The speaker will provide a project management overview of the challenges and successes of moving multiple research programs to her institution, all at the same time. Topics will include project planning and management of both clinical/research staff, laboratory moves, the regulatory documents needed, involvement and roles of multiple departments and knowing when to leverage key personnel to assist in program management to ensure successful outcomes.