

# Global Pharma Summit

August 10-12, 2015 Philadelphia, USA



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## **Best practice approaches to the coordination and execution of human clinical trials in the 'start-up' setting**

The day to day pressure and challenges inherent to the management of a clinical operations department are amplified in the entrepreneurial world of the biotech 'start-up' organization. In a vacuum of resources, time and finances, defining and delivering on the strategy for a scientifically sound plan of early to advanced phase trials that will yield robust safety, proof of concept and mechanism data is critical to the future of the organization and the realization of product potential. There are many opportunities for error and few opportunities for second chances. With so much at stake, knowledge of the full scope of the product lifespan, the foundation of interdepartmental respect and collaboration and setting forth unyielding standards of excellence and integrity are fundamental to success in any setting; and imperative in the 'start-up' environment. The objective of this presentation is to outline best practice strategies for success in the management of clinical trials in the entrepreneurial arena; to use case studies for illustrating 'lessons learned' and to assist in the recognition of and triumph over common pitfalls that are endemic to this work environment.

### **Biography**

R Lisa Kaufman has pharmaceutical industry professional experience of more than 25 years' in large, mid-sized and start-up organizations; clinical trial Phases 1-4. Career appointments reflect the full spectrum of clinical operations roles from Quality Assurance oversight of a 42 bed in-patient Phase I clinic, to experience serving as a Clinical Research Associate, work in Project/Program Management, leading to Executive Management leadership positions in clinical operations and clinical affairs. She also maintains her Board Certification and professional licensure as an Acute Care Nurse Practitioner with a practice focus in Internal and Emergency Medicine; and teaches in the academic setting on request.

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