



NEW COURSE OFFERING

CLINICAL TRIAL MANAGEMENT

410.606.71 CLINICAL TRIAL MANAGEMENT

Cost: \$2,715

Instructors: Steven E. Linberg, Kristin Canchola

Thursday 6:00-8:45 pm; September 10–December 17

This course provides an overview of the planning and management of clinical trials in the US and internationally. Students learn about the processes involved in planning the trial, creating case report forms, developing the clinical database, selecting and initiating sites, monitoring sites, cleaning the database, analyzing the data, and writing the final study report. At the end of this course students will better understand the aspects involved in managing clinical trials under federal regulations, international (ICH) guidelines, and good clinical practices.

About Steven E. Linberg, Ph.D.

Chiesi Pharmaceuticals, Inc., Vice President, Managing Director and Treasurer

Dr. Linberg has more than 30 years of academic clinical research, and drug and biologics development experience, with expertise in directing overall program development, and in individual trial design, execution and reporting. Dr. Linberg's experience includes the primary direction of complete drug development programs from IND to NDA that resulted in FDA approval. Prior to joining Chiesi, Dr. Linberg initially worked as a faculty member and clinical investigator in academia. He has since held senior positions in the drug and biologics industry and at contract research organizations. Dr. Linberg is the Editor and a contributing author to the text *Expediting Drug and Biologics Development*, now in its 3rd edition, and teaches graduate courses in drug development and clinical trial design at Johns Hopkins University.

About Kristin Canchola, M.S., C.C.R.A.

Clinical Research Manager

Ms. Canchola has more than 6 years' experience in clinical research and is currently acting as a Clinical Research Manager on phase II and III studies. Prior to her management experience, she has more than 4 years' experience in clinical site monitoring as well as experience in project coordination. Prior to joining Cato Research, she had 4 years' experience in preclinical drug development working as a project leader on the scientific development of viral-based drugs as antibacterial agents. She holds a Master of Science degree in biotechnology from The Johns Hopkins University where she completed graduate course work in cancer biology, clinical trial design, clinical drug development, regulatory affairs, and Good Manufacturing Practices. At Cato Research, Ms. Canchola has worked as a project coordinator on various clinical studies as well as Food and Drug Administration (FDA) submissions. She acted as a clinical research associate, monitoring phase I through III drug and device studies. She has monitored studies in various therapeutic areas including chronic pain, acute pain, oncology, cardiology, vaccine, and infectious disease. Ms. Canchola is now acting as a clinical research manager and has managed HIV gene therapy and acute pain studies.

For questions about the course or how to register contact:

Dr. Lynn Johnson Langer

Senior Associate Program Chair

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or visit our website to register online

advanced.jhu.edu/registration