

Writing Preclinical Reports for IND Submissions

Fall 2010

About the Program

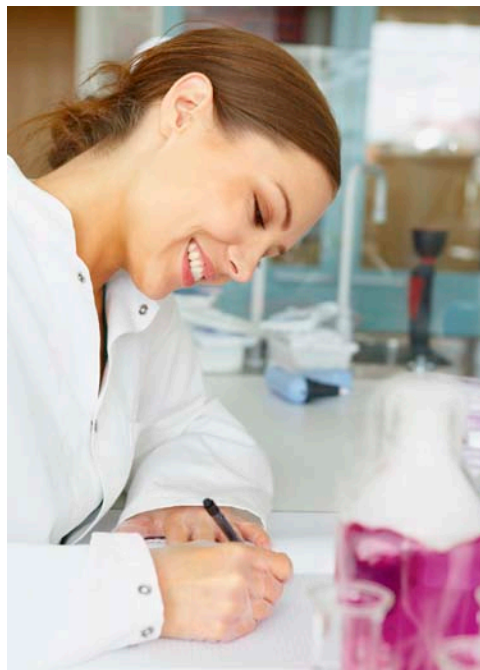
Pre-Clinical Study reports are key elements of IND submissions and differ from scientific papers. Writing pre-clinical reports requires being thorough, rigorous, consistent, unbiased, and detail-oriented. This course provides a detailed practical approach to generating pre-clinical study reports by reviewing every step of the process, from data collection to final approval. The structure of reports, the type of information to be reported, and the regulatory requirements will be discussed in depth. Participants will learn how to collect, verify, present and interpret data according to regulatory requirements. Through examples and writing exercises, participants will become familiar with reporting styles and practice word selection.

Program Objectives

The goal of this course is to teach professionals the practice of drafting and writing a pre-clinical/non-clinical study report, to compare and contrast study reports to a typical scientific manuscript, and introduce and overview the key regulatory needs that a pre-clinical study report must fulfill.

By the end of this course, the student will be able to:

- Be able to identify the critical topics that must be included in a study report
- Be able to identify resources to guide study report writing (study protocols, regulatory)
- Be able to identify key team players that will be necessary to provide material for the study report
- Be able to distinguish the differences in various preclinical programs to write customized study protocols and study reports
- Be able to identify the different regulatory needs for each study report
- Be able to identify and discuss best practices in writing preclinical study reports



Who Should Attend?

This course is valuable to any individual who may be involved in the generation or review of pre-clinical reports in the biotech and pharmaceutical industry, including:

- Scientists
- Regulatory affair personnel
- Clinical and R&D managers
- Medical Writers

Fall 2010 Course Details

Dates and Times

Fridays, September 24 – November 5
8:00 a.m. – 10:30 a.m.

Note: 6 to 9 course hours required online

Location

Room 106
UCSD Extension Sorrento Mesa Center
6925 Lusk Blvd., San Diego, CA 92121

Fee

\$395

Program Schedule

Session I (SEPT 24th, 8AM – 10:30AM)

- Overview of the IND Process: from proof of concept to FDA submission (**J.Cunningham**)
- Structuring the Study Report: study protocols as the guideline (**J.Cunningham**)
- Starting from the End: Anticipating the FDA audit, standards & GLPs (**Mindy Resh, Abraxis Bioscience**)

Session II (OCT 01st, 8AM – 10:30AM)

- Regulatory requirements in reporting nonclinical laboratory study results (**TBA**)
- Industry standards for effective reports: it's all in the study design (**J.Cunningham**)

Session III (OCT 8th, 8AM – 10:30AM)

- The writing process: Document templates, drafting a story, & effective headings (**J.Cunningham**)
- The Art of Writing: Best practices of a well written study report (**Eugene Brandon, ViaCyte Inc**)

Session IV (OCT 15th, 8AM – 10:30AM)

- Dealing with data: Reporting research design, summarizing data, focusing on outcomes (**J.Cunningham**)
- Reporting statistics: Best practices in statistics for study reports (**Elizabeth Ludington, Somaxon Pharm.**)

Session V (OCT 22nd, 8AM – 10:30AM)

- Wrapping up the story: summarizing, concluding, reviewing & managing the cycle (**J.Cunningham**)
- Commercial software support for study report generation (**Diana Micehlotti, iAdvantage software**)

Session VI (OCT 29th, 8AM – 10:30AM)

- Tailoring the Efficacy Study Report (**J.Cunningham**)
- Tailoring the Dose/Toxicity Study Report & Incorporating the Pathology Report (**Carol Meschter DVM, Comparative Biosciences**)

Session VII (NOV 5th, 8AM – 10:30AM)

- "e-submissions" Overview of preparing your study report for an e-submission (**J.Cunningham**)
- Technical requirements: preparing data tables, hyper linking study reports, study tagging files, regional requirements (USA, Europe, Japan, Australia) (**Todd Phillips, Image Solutions Inc.**)

Session VIII: Online component

- GLP's and regulatory requirements
- Assigned pre-written introductory paragraph for a study report
- Assigned statistical analysis & written paragraph for data summary
- Draft study report critique

Instructors

Justine Cunningham, Ph.D., founded Preclinical Sciences in response to the growing demand for preclinical expertise for novel & challenging bio-therapeutics. Dr Cunningham is an experienced biotechnology professional in the preclinical testing of complex biologics for First in Human clinical application. She was integrally involved in the preclinical development program for a genetic therapy directed toward Parkinson's disease that led to a successful IND filing & more recently for the development of human embryonic stem cell based therapy for diabetes.

Eugene Brandon, Ph.D., is currently Associate Director of Product Development at ViaCyte, Inc., where he is project manager for the diabetes cell therapy program. Dr. Brandon has 25+ years of biomedical research and development experience, with particular knowledge in stem cells, molecular biology, neurobiology, neurodegenerative diseases, diabetes, and cell and gene therapy. His expertise spans from practical technical laboratory matters to the larger-picture challenges of translational implementation. As project manager for several complex cutting-edge biomedical products, he is aware of the many issues that can affect the entire spectrum of a biotechnology project. Dr. Brandon has conceived, written, and assembled numerous scientific, regulatory, and business development documents including peer-reviewed journal articles, study reports, INDs, Appendix Ms, white papers, corporate overviews, and NIH, SBIR, private foundation, and CIRM grant applications.

Elizabeth Ludington, Ph.D., is currently the Executive Director of Technical Operations at Somaxon Pharmaceuticals, where she leads all statistical and regulatory activities. She has worked in all phases of drug development, from discovery and pre-clinical development through post-approval stages. She has participated in writing and submitting multiple INDs and NDAs. She received her PhD in Biostatistics from the University of Iowa and has 10+ years of experience as a statistician in the Pharmaceutical and Biotech industries.

Carol Meschter DVM, Ph.D., DACVP, is founder of Comparative Biosciences. Previously, she was in the Investigative Toxicology Group at Hoffmann-LaRoche, and was the Director of the Research Animal Facility at the American Health Foundation in Valhalla, NY. As a board-certified veterinary pathologist, she brings 15+ years of experience in the pharmaceutical industry, primarily in toxicology, pathology, preclinical development, discovery support, and preclinical pharmacology. She is knowledgeable in early phase drug development from discovery to NDA, with technical expertise in pathology, pharmacology, efficacy modeling, and pharmacokinetics. She is a scientific editorial reviewer for Toxicologic Pathology, Veterinary Pathology, AVMA Journal, AJVR, J Applied Immunology, and has 100+ publications.

Diana Michelotti is currently Director of Marketing and Sales at iAdvantage software. She has over 25 years experience in Strategic Marketing, Sales and Distribution Channel Development. iAdvantage Software is a 100% Web-Based Electronic Study Management (eStudy) and Reporting Tools (ePublisher) for preclinical studies. It improves productivity, reduces time-to-results, stream-lines the management & reporting of preclinical studies while benefiting scientists, quality assurance, operations, management, sponsors and investors. Previously, she has successfully negotiated multi-million dollar OEM contracts with Global Fortune 500 Companies in the Data Communication Industry and mapped business processes to custom software solutions in end-to-end On-line Transactional Processes in Directory Publishing.

Todd Philipps is currently a regulatory consultant at Image Solutions where he helps pharmaceutical and biotechnology companies worldwide make use of the latest electronic submission and product information tracking tools and techniques to bring new medicines and treatments to market faster, safer and at a lower cost. He has a background in information management and regulatory operations, and is expert at helping existing and emerging life science companies maximize the utility of new electronic drug registration formats to both cut cost and improve product tracking. Todd also is skilled at explaining the drug development industry's transition to a paperless system and the impact that is having on both the availability and safety of new drugs and therapies.

Melinda Resh, MBA, is the Associate Director of Preclinical QA for Abraxis Health, a company specializing in oncology diagnostics and therapeutics. Ms. Resh has over twenty years of experience in quality assurance in the pharmaceutical/biotechnology and clinical laboratory industries. Her experience encompasses all facets of quality assurance and compliance to Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice, Good Tissue Practice Regulations and Clinical Laboratory Improvement Amendments. In addition, she has participated in the successful filing of Investigational New Drug applications. Ms. Resh holds a B.S. in Microbiology from San Diego State University, an MBA from the University of Redlands and is an active member of the Society of Quality Assurance (SQA) and the Regulatory Affairs Professional Society (RAPS). She is also a licensed Clinical Laboratory Scientist for the state of California and a licensed Medical Technologist by the American Society of Clinical Pathologists.

For more information:

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