FDA's Clinical Investigator Training Course
This extensive 3-day course focuses on nonclinical, early clinical, and phase 3 studies; issues in the design and analysis of trials; safety and ethical considerations; and FDA's regulatory requirements related to the performance and evaluation of clinical studies. Attendees will have the unique opportunity of hearing directly from FDA's nationally renowned experts on issues critical to successful clinical research. The course is designed for physicians, nurses, pharmacists, and other health care professionals involved in clinical trials.

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Nov. 12-14, 2013 Clinical Investigator Training Course - Slides

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Agenda

2013 Clinical Investigator Training Course Agenda (PDF - 135KB)

FDA Structure and Mandate (PDF - 1.7MB) Leonard Sacks, Office of Medical Policy CDER, FDA

The Design of Clinical Trials (PDF - 1.1MB) Robert Temple, MD (CDER)

Clinical Trial Endpoints (PDF - 147KB) Eugene J. Sullivan, MD FCCP Principal EJS Consulting, LLC

Issues in Clinical Trial Designs for Devices (PDF - 392KB) Owen Faris, Ph.D.,Deputy Director, Division of Cardiovascular Devices, Office of Device Evaluation, CDRH, FDA

Issues in Clinical Trial Design for Companion Diagnostic Devices (PDF - 309KB) Sally A. Hojvat, Ph.D., CDRH, FDA

Informed consent and ethical considerations in clinical trials (PDF - 2.1MB) Dale Hammerschmidt, M.D., University of Minnesota, MN

Safety Considerations in Phase 1 Trials (PDF - 161KB) Sumathi Nambiar, M.D., MPH, Acting Director, Division of Anti-Infective Products

Safety Assessment in Clinical Trials and Beyond (PDF - 153KB) Yuliya Yasinskaya, M.D., Medical Officer, Division of Anti-infective Products, CDER

Clinical Discussion of Special Populations (PDF - 766KB) Ryan P. Owen, Ph.D.. Office of Clinical Pharmacology, Office of Translational Sciences,CDER

FDA Perspective on International Studies (PDF - 1.1MB) Kassa Ayalew, M.D., M.P.H. (CDER)

Good Clinical Practice (GCP) Key Topics (PDF - 91KB) Bridget Foltz, (OC)

Investigator Responsibilities – Regulation and Clinical Trials (PDF - 5.1MB) Cynthia Kleppinger, M.D., (CDER)

The Analysis of Investigator Data, Sources of Bias and Error (PDF - 291KB) Susan Ellenberg, Ph.D.,(University of Pennsylvania)

CMC and the investigator Brochure (Drugs): Ensuring the Quality of a Drug used in a Clinical Trial (PDF - 244KB) Dorota Matecka, Ph.D., Office of New Drug Quality Assessment, CDER

Biosimilar Biological Products (PDF - 294KB) Sue Lim, (CDER)

Pharmacology/Toxicology in the Investigator Brochure (PDF - 149KB) Brenda Gehrke, Ph.D., (CDER)

Clinical pharmacology 1: Phase 1 studies and Early Drug development (PDF - 420KB) Gerlie Gieser, Ph.D., (CDER)

Clinical pharmacology 2: Clinical Considerations During Phase 2 and Phase 3 of Drug Development (PDF - 451KB) Kellie Reynolds, Pharm.D.,(CDER)

How do I put together an IND application? (PDF - 109KB) Judit Milstein, (CDER)

Clinical Investigator Inspections: What to Expect (PDF - 36KB) Constance Cullity, M.D., (CDER)

How to put together an Application (PDF - 257KB) Donald Fink, Ph.D., (CBER)

Preparing an IND Application: Preclinical Considerations for Cell and Gene Therapy Products (PDF - 303KB) Patrick Au, Ph.D., (CBER)

Preparing an IND Application: Clinical Considerations for Cell and Gene Therapy Products (PDF - 914KB) Rachel Witten, M.D., (CBER)

Roles and Responsibilities for Devices (PDF - 396KB) Lynn Henley, (CDRH)

How to Put Together an IDE Application (PDF - 434KB) Nichole Chamberlain, (CDRH)

Ensuring the Safety of Clinical Trials: AE Reporting, DSMBs, IRBs (CDER) (PDF - 244KB) Mathew Thomas, (CDER)

Ensuring the Safety of Clinical Trials: AE Reporting, DSMBs, IRBs (CBER) (PDF - 103KB) Patricia Holobaugh, (CBER)

Special Cardiac Safety Concerns (PDF - 276KB) Shari Targum, M.D., (CDER)

Serious Drug Induced Liver Injury (PDF - 1MB) Lana Pauls, MPH, (CDER)

A Patient Advocate's Perspective on Clinical Trials (PDF - 135KB) Jane Reese-

Coulbourne, Reagan-Udall Foundation

The Clinical Investigator's Role in Drug Development (PDF - 138KB) Title Slide

The Physician as Clinician and Investigator (PDF - 81KB) Douglas Peddicord, Ph.D., ACRO

The Investigator as collaborator in promoting the clinical research enterprise (PDF - 111KB) Neil J. Weissman, M.D., MedStar Health Research Institute

The Investigator: A Trusted Partner (PDF - 164KB) Christine Pierre, SCRS

The Investigator as the Custodian of the Data Chain (PDF - 166KB) Sabrina Savic-Comic, MD, The Medicine Company