



The Red River Valley Chapter
of the Association of Clinical Research Professionals

is hosting a

Research Symposium

When: Friday September 30th – Saturday October 1st

Where: Cetero Research, Bentley Auditorium at 4801 Amber Valley Parkway, Fargo, ND

Program Description: This educational event offers five different presentations on various topics in drug development and clinical research including FDA Inspections, IRB process, Quality Assurance, discovery and development of a new drug, and heart rhythm study design and challenges. Event speakers come from a variety of backgrounds and offer years of experience.

Target Audience: This event is intended for Clinical Research and Pharmaceutical Industry Professionals but offers continuing education credits for a variety of clinical professionals.

Day 1: Friday September 30 th 2011	
Time	Activity
12:30 - 1:15 pm	Registration Check-in
1:20 - 2:50 pm	Lisa Korcuska, CIP, MS, Director of Research Compliance at Sanford Health FDA Inspections of Clinical Trials Objectives: 1) Demonstrate an understanding of when an FDA inspection is conducted, 2) Summarize the FDA clinical site inspection process, and 3) Describe how a clinical trial site can prepare for an FDA inspection.
2:50 - 3:00 pm	Break
3:00 - 4:30 pm	Debra Langstraat, CIP, Director, Human Research Protection Program at Sanford Health How the IRB Process Protects Objectives: 1) How the IRB regulations work to protect human subjects in research, 2) How the IRB makes determinations for level of review and risk, and 3) When to submit additional information to the IRB.
6:00 – 9:00 pm	Social at Fargo Billiards & Gastropub (3234 43 rd Street South, Fargo, ND)
Day 2: Saturday October 1 st 2011	
Time	Activity
7:30 - 8:00 am	Registration Check-in
8:00 – 9:30 am	Alan Copa, PharmD, President, Clinical Operations at Cetero Research Thorough Qt Trials Objectives: 1) Review the history of the Thorough QT study, 2) Summarize the keys to successful clinical execution of the Thorough QT study, 3) Recognize critical factors in the design of the Thorough QT study protocol, and 4) Discuss the current status of the Thorough QT study: Where are we today?
9:30 – 9:40 am	Break with Coffee and Donuts/Muffins
9:40 – 11:10 am	Christopher Both, MS, RQAP/GCP, Regional Director, Quality Assurance at Cetero Research Quality Assurance Objectives: Recognize trends in Good Clinical Practice GCP related FDA warning letters related to 1) sponsors, 2) monitors, 3) IRBs and 4) Identify areas to improve and add more value to monitoring and site visits.
11:10 – 11:20 am	Break
11:20 – 12:50 pm	Satish Chandran, PhD, Director of the Center of Excellence for Biopharmaceutical Research & Development at NDSU and Professor of Pharmaceutics at NDSU Discovery and Development of a Novel Drug Candidate Objectives: 1) Identify examples of how new drugs are discovered, 2) Understand how a new drug is developed, 3) Understand the regulatory and clinical strategies involved in evaluating the safety and efficacy of a new drug, and 4) Identify some of the challenges during development of a new drug using a novel MoA (first in class) as an example.

Registration and Fees: Attendees can register for one of three options. Option 1: Day 1 Presentations only \$40.00, Option 2: Day 2 Presentations only \$55.00, or Option 3: Day 1 and 2 Presentations for the discounted price of \$75.00. All options include admission to the Social held Friday evening and cost of Continuing Education (CE) credits.

Register by Friday September 23rd by contacting Aaron Bjugstad at aaron.bjugstad@cetero.com with your attendance option (1, 2, or 3) and contact information. Payments (cash or check made out to RRV ACRP) can be sent to Cetero Research, C/O Aaron Bjugstad, 4801 Amber Valley Parkway, Fargo, ND. Registration for this program is non-refundable.

Contact Hours: NDSU* has approved this program for contact hours (CE credits). The program number is 0047-9999-11-138-L04-P. Each presentation is worth 1.5 contact hours for a total of 7.5 CE credits if all presentations are attended. Attendance at the presentation and completion of the evaluation form will be required to receive CE credit. An ACPE statement of credit will be mailed to those participating in this program within 4-6 weeks of receipt of all evaluation materials.



*North Dakota State University College of Pharmacy, Nursing, and Allied Sciences is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This program is sponsored in part by Cetero Research and Walgreens.