Current Issues In Clinical Research

Latest Trends In Clinical Research

October 4–5, 2006
Minneapolis Convention Center
Minneapolis, Minnesota

A program co-sponsored by Mayo Clinical Trial Services, Mayo Center for Patient Oriented Research, and the University of Minnesota Academic Health Center

In cooperation with Mayo Continuing Nursing Education
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REGISTRATION FORM

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CONFERENCE DESCRIPTION
This conference will focus on emerging trends and provide a comprehensive review of the responsibilities and processes of clinical research performance. The program will include information on evolving strategies of pharmacovigilance, current issues in genomics and proteomics, the pros and cons of eClinical trial initiatives, principles of good clinical practice, and the mechanics of teamwork in clinical research. Formatted into 1.5 days, the conference will balance topics of common interest in general sessions with specific clinical research and management issues in breakout sessions. Time will be allotted at the end of each presentation for questions and discussion.

CONFERENCE LEARNING OBJECTIVES
Upon completion of the conference, participants should be able to:
- Examine emerging trends of research
- Illustrate the principles of good clinical practice
- Interpret current issues in genomics and proteomics
- Recognize the ethical tensions related to special populations
- Discuss the scientific and regulatory challenges of combination products
- Demonstrate the pros and cons of credentialing

DISCLAIMER
Attendance at this conference does not indicate nor guarantee competence or proficiency in the performance of any procedures that may be discussed or taught in this conference.

INTENDED AUDIENCE
This program is designed for clinical research professionals, including principal investigators, study coordinators, nurses, and other research personnel involved in managing and coordinating clinical research.

CREDIT
Mayo Clinic College of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Mayo Clinic College of Medicine designates this educational activity for a maximum of 11.25 hours of AMA PRA Category 1 Credit™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Mayo Continuing Nursing Education is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center’s (ANCC) Commission on Accreditation.

Participants can earn up to 13.6 accredited nursing contact hours.

The Society of Clinical Research Associates (SoCRA) accepts documentation of candidate participation in continuing education programs for recertification if the program is applicable to clinical research regulations, operations or management, or to the candidate’s clinical research therapeutic area.

Association of Clinical Research Professionals accepts ANCC and ACCME contact hours.

DATE AND LOCATION
The Current Issues in Clinical Research conference will be held October 4–5, 2006. Conference headquarters will be located in Room 200 on the upper level of the Minneapolis Convention Center, 1301 Second Avenue South, Minneapolis, Minnesota.

REGISTRATION
To register, complete the attached registration form and return by mail or fax. The registration fee of $550 includes tuition, comprehensive conference syllabus, continental breakfasts, lunches, and break refreshments. Although it
is not the policy of Mayo Clinical Trial Services, Mayo Center for Patient Oriented Research, or the University of Minnesota to limit the number of participants, conference room facilities may necessitate closing of enrollment; therefore, early registration is strongly advised. **Registration deadline is September 8, 2006.** Please indicate your e-mail address on the registration form. A letter of confirmation will be forwarded to your e-mail address upon receipt of payment and completed registration form. Present the letter of confirmation when checking in at the meeting registration desk.

**CANCELLATION POLICY**
If you cancel your participation in this conference on or before **September 8, 2006**, your registration fee, less a $75 administrative fee, will be refunded. Mayo Clinical Trial Services Education Department must receive written notification of your cancellation. No refunds will be made after September 8, 2006.

**TRAVEL**
Minneapolis, Minnesota, is located in the heart of North America and regarded as one of the nation’s safest and cleanest cities. It boasts excellent shopping, restaurants, museums, live theaters, and music venues. Located only 11 miles from downtown, the Minneapolis/St. Paul International Airport (MSP) is serviced by nine major and seven regional carriers.

For travel arrangements, you may contact Lori Munsen at Corporate Travel at 800-526-4540 or 507-287-7462 (direct); 507-282-9020 (fax); or e-mail: lori@ctsrst.com. Identify yourself as attending this Mayo Clinical Trial Services conference.

Travel arrangements are the responsibility of the registrant.

**LODGING ACCOMMODATIONS**
A guest room block has been reserved for participants and their guests with special conference rates at the downtown Hilton Minneapolis. To receive the special rate, you must make reservations before the room block is filled or before the expiration date of Tuesday, September 5, 2006, whichever comes first. Reservations will be taken following this date based on space and rate availability. Please identify yourself as a participant of the Current Issues in Clinical Research conference when making a reservation. If making reservations online, please use the group convention code to receive the special rate (group code – MAY).

**Hilton Minneapolis**
1001 Marquette Avenue South
Minneapolis, MN 55403
800-445-8667 or 612-376-1000
www.hilton.com
$155 single/double

The Hilton Minneapolis hotel is connected by skyway to the Minneapolis Convention Center. For additional accommodation options, you may also wish to visit the official visitor Web site for Minneapolis (www.minneapolis.org). Lodging arrangements are the responsibility of the registrant.

**PARKING**
Parking is available in hotel, city, and Minneapolis Convention Center ramps. The cost for parking is not included in the registration fee. A map indicating the location of parking facilities will be mailed with the registrant confirmation letter.

**PLACES TO VISIT**
Mall of America is the largest fully enclosed retail and family entertainment complex in the United States. Along with 500 retail stores, restaurants, and nightclubs, the mall features...
The Park at MOA, the world’s largest indoor theme park, and Underwater Adventures Aquarium, a walk-through aquarium featuring 15,000 fish. The Mall of America is just a 30-minute light-rail ride from downtown Minneapolis.

Minneapolis is home to more than 57 museums within the area. This includes art museums, scientific institutions, historical museums, and historical sites. Of note is the Museum of Russian Art, the only North American museum dedicated solely to Russian art from the Soviet period. Another highlight is the Frederick R. Weisman Art Museum, which features early 20th century American artists as well as a sundry collection of contemporary art.

Among other activities in the city is its theatre district which hosts touring Broadway shows and national musical acts. Minneapolis also has many exceptional restaurants, ranging from American to sushi.

**FACULTY**

**COURSE DIRECTORS**
Stephen L. Kopecky, MD, FACC  
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Assistant Vice President for Research  
Academic Health Center  
University of Minnesota  
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Academic Health Center  
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Departmental Due Diligence Officer  
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Professor  
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Chief Quality and Regulatory Officer  
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Harvey M. Meyerhoff Professor of Bioethics and Medicine
Phoebe R. Berman Bioethics Institute and Department of Medicine
Johns Hopkins University
Baltimore, Maryland

Sidney M. Wolfe, MD
Director
Health Research Group
Public Citizen
Washington, D.C.

FACULTY DISCLOSURE
As a provider accredited by ACCME, Mayo Clinic College of Medicine (Mayo School of CME) must ensure balance, independence, objectivity, and scientific rigor in its educational activities. Conference director(s), planning committee, faculty, and all others who are in a position to control the content of this educational activity are required to disclose all relevant financial relationships with any commercial interest related to the subject matter of the educational activity. Safeguards against commercial bias have been put in place. Faculty also will disclose any off-label and/or investigational use of pharmaceuticals or instruments discussed in their presentation. Disclosure of this information will be published in conference materials so that participants in the activity may formulate their own judgments regarding the presentation.
WEDNESDAY, OCTOBER 4, 2006

CONFERENCE AGENDA

7:00 AM  REGISTRATION AND BREAKFAST  
Foyer, Upper Level  
Minneapolis Convention Center

8:00 AM  Welcome and Introduction  
Mark S. Paller, MD, MS

8:15 AM  Genomics, Proteomics, and Metabolomics to Characterize On- and Off-Target Drug Effects – Routine Application in Future Drug Development  
Pieter Muntendam, MD

9:15 AM  The NIH Roadmap for Re-engineering Clinical Research – Where is it Going?  
Barbara M. Alving, MD, MACP

10:15 AM  BREAK

10:35 AM  Research-Based Patient Advocacy  
Sidney M. Wolfe, MD

11:35 AM  LUNCH  
Seasons Room  
Minneapolis Convention Center

12:45 PM  Breakout Session

1:50 PM  Breakout Session

2:40 PM  BREAK

3:00 PM  Professionalism in Clinical Research  
E. Greg Koski, PhD, MD, CPI

4:00 PM  The Impact of Pharmacogenomics at the FDA  
Michael S. Orr, PhD, DABT
THURSDAY, OCTOBER 5, 2006

6:45 AM  BREAKFAST  
Foyer, Upper Level  
Minneapolis Convention Center

7:30 AM  Ethical Tensions Related to Research Involving Special Populations  
Jeremy Sugarman, MD, MPH, MA

8:30 AM  Combination Products – Scientific and Regulatory Challenges  
Murray M. Lumpkin, MD

9:30 AM  BREAK

9:50 AM  Breakout Session

10:50 AM  Breakout Session

James C. Gerner, EdD, MS, MT(ASCP)

12:50 PM  Adjournment (Box lunch available)
BREAKOUT SESSION DESCRIPTIONS

WEDNESDAY, OCTOBER 4
12:45–1:35 PM

How to Participate in an Audit – Lynn M. Padley
This breakout session will cover the fundamentals of clinical trial audits including descriptions of the different types of audits and how to prepare for an audit, and the difference between an audit visit and a monitoring visit. How participants should conduct themselves in an audit will be reviewed.

Randomized Clinical Trials: Designs for the Future and Obstacles to Overcome – James D. Neaton, PhD
With recent advances in the basic sciences and improved diagnostic technology, the potential for future improvements in health is great. However, major gaps exist in optimally translating knowledge about new technologies into clinical practice. Pragmatic or practical clinical trials are needed to determine if treatments do work, in contrast to trials designed to determine whether treatments can work. In this breakout session, the rationale for more pragmatic or practical trials will be presented, design and implementation issues will be outlined, and obstacles to the conduct of such studies will be reviewed.

Maximum Teamwork: Building Groups that Achieve More than You Thought Possible – Greg A. Shelley, PhD
Participants will learn the processes surrounding effective and productive group development. By learning how groups change over time and how to develop trust, commitment, consensus, accountability, and confidence among group members, participants should leave with practical skills to develop high-achieving teams.

1:50–2:40 PM

How to Participate in an Audit – Lynn M. Padley
This breakout session will cover the fundamentals of clinical trial audits including descriptions of the different types of audits and how to prepare for an audit, and the difference between an audit visit and a monitoring visit. How participants should conduct themselves in an audit will be reviewed.

Effective monitoring of a clinical investigation protects people who volunteer to participate in research studies and ensures the quality and integrity of the study data. Management of potential risk starts as early as the device design/development phase, and successful study sponsors leverage this wealth of information to maximize trial design and monitor trial conduct. Upon completion of this session, participants will be able to understand roles and recommended best practices used by study sponsors, study monitors, study investigators, and hospital staff.
Leadership that Lasts: Influencing Others Today to Make an Impact Tomorrow – Greg A. Shelley, PhD
Participants will learn what it means to lead others, as well as develop leaders for the future. In discussing effective leadership qualities and styles, communication barriers and skills, and applied leadership techniques, participants will be challenged to assess their own leadership effectiveness and develop practical leadership skills to use and promote with others.

THURSDAY, OCTOBER 5
9:50–10:40 AM

Medical Device Clinical Trials – An Evolution – Susan Alpert, PhD, MD
Medical device clinical trials have increased in both number and sophistication over the past five years. As products move from tool function to disease management and full therapy, the need for different types of data for different partners is clear. Discussion will include the impact of these changes on the industry and the regulators.

Investigational New Drug Applications: What, Why, and How – Harvey M. Arbit, PharmD, MBA
The submission of an investigational new drug (IND) application is required for certain clinical trials. Understanding what an IND is, why it is needed, and how to put it together takes the mystery and frustration out of the process. The presenter will take participants through the process, explaining each step along the way. An investigator-initiated IND application should not be an obstacle that prevents clinical trials from taking place.

Pharmacovigilance After Vioxx – B. Gil Price, MD
Good pharmacovigilance practices and assessment of observational data regarding drugs is at an all-time high. This presentation will focus on (1) basic pharmacovigilance, (2) safety signal identification, and (3) pharmacovigilance plan development.

10:50–11:40 AM

Ethics of Clinical Trials – Mary Faith Marshall, PhD
Ethical issues are paramount in clinical trials. This breakout will cover some of the current ethical dilemmas associated with clinical trial research.

Informed consent is a cornerstone upon which ethical care and ethical research are built. But it is also an elusive goal, for which our best efforts sometimes yield only a rough approximation. Attempts to limit liability through the consent process and form are a perennial problem, as is the difficulty distinguishing between research consent and treatment consent. In the age of the Internet, “information” from unexpected sources may prejudice the consent process. International research and new immigrants may provide context where our assumptions and algorithms fall flat. The speaker will try to help make sense out of these issues.
eClinical Trial Initiatives – Rebecca D. Kush, PhD

eClinical trials are defined as those trials in which primarily electronic processes are used to plan, collect, access, exchange, and archive data required for the conduct, management, analysis, and reporting of the trial. There are actually very few “pure” eClinical trials occurring today. Research results from industry surveys on the adoption and attitudes of sites and sponsors with respect to the implementation of new technology to clinical trials will be presented and key factors that would facilitate the conduct and value of eClinical trials will be addressed.

ABSTRACTS

As part of the Current Issues in Clinical Research conference, participants are invited to submit a poster abstract for review, demonstrating interests or work related to clinical research. The presentations can be scientific study results or information and ideas on improving clinical research and patient care.

The goal of the poster event is to educate and inform about research, discuss innovations for sharing ideas and interests, and network with other participants.

For additional details on the call for abstracts and to submit an application, please visit the Web site: www.mayocts.com/education/conferences. Any questions regarding the submission of abstracts can be directed to Becky Chapel in the Mayo Center for Patient Oriented Research at 507-538-8145 or via e-mail at chapel.becky@mayo.edu.
**Current Issues In Clinical Research**  
**Latest Trends In Clinical Research**

**MINNEAPOLIS CONVENTION CENTER • MINNEAPOLIS, MINNESOTA • OCTOBER 4–5, 2006**

**Mail form and payment to:**
Mayo Clinical Trial Services Education Department  
3050 Superior Drive NW, Rochester, MN 55901

**Telephone:** 800-541-5815 or 507-284-0286  
**Fax:** 507-284-8016 • **E-mail:** strain.diane@mayo.edu  
**Web site:** www.mayocts.com/education/conferences

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### CONTACT INFORMATION  
(Please print or type all information. You may duplicate this form for multiple registrations.)

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<tr>
<th>Name</th>
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**E-mail** (required)

**Telephone:** Home ( ) Business ( )  
If international number, please include country and city code.

**Special needs**  
Please advise if you have special accommodation or dietary needs and indicate specific need(s):

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**BREAKOUT SESSIONS REGISTRATION**  
(Please indicate your preference of breakout topic for each time slot.)

**Wednesday, October 4**

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<td>A Grimm Perspective on Informed Consent – D. Hammerschmidt, MD, FACP</td>
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### PAYMENT INFORMATION  
- Credit Card  
- Check Enclosed (payable to Mayo Clinical Trial Services)

**REGISTRATION FEE** $550

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<th>Payment Method</th>
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**Name of Cardholder (as it appears on the card)**  
**Signature of Cardholder (required)**  
**Date**

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**Special needs**  
Please advise if you have special accommodation or dietary needs and indicate specific need(s):