President's Message - Lyn Goldsmith

Thanks to all the attendees of our 2nd Job Fair and Networking Party. The event was very well attended, vendor slots were sold out, and Flatotel was a lovely and gracious venue for the event. Rachael Yoo, our Marketing Committee Chair found the location, negotiated the contract, and attended to all the details that makes an event successful. Rachael deserves much credit for a job well done. She's now working on securing a location for the Holiday Networking Party on December 2nd, 2010. If you've considered getting more involved in the chapter and would like to join a committee, the Marketing committee is a great place to start, especially if you like event planning.

For those who couldn't make the June 3rd event, please be sure to check out our new Job Board. There are many great positions available right now.

We are very excited about this year's two day symposium; each panel has highly distinguished speakers who will approach the subject of Clinical Research Site Excellence from a different perspective. Erika Stevens, Halley Rogers, and Alison Randall have put together a great program; please pass the word on to your friends and colleagues. The chapter remains committed to keeping prices as low as possible to encourage and enable people to attend even if their employer offers limited support for continuing education.

On October 7th, 2010 we will have our final educational event of the year; the topic is Investigator Initiated Research. Please see the education committee write up for more information. The chapter board has more than doubled in size in the last few years and our job is to keep the chapter growing and evolving. New members always bring fresh ideas and energy, so consider getting involved.

Finally, if you have any comments, suggestions, ideas, or complaints, you can write us at nymetroacrp@gmail.com. Someone will always reply to your email.

Lyn Goldsmith
Chapter President
On May 6th Columbia University hosted a presentation on "Research Billing Compliance" by David Vulcano, an expert in the field. The presentation focused on the current Medicare billing requirements for services pertaining to clinical research, with a special focus on real-life scenarios in which these rules and regulations apply. Mr. Vulcano cited explanations for these rules directly from the official documentation, and provided attendees with guidance on where to find more information that is relevant to their particular research needs.

We have two exciting educational events left in 2010! The first event is the New York Metropolitan Chapter's Annual Fall Symposium, which will be held on Friday, September 24th and Saturday, September 25th at New York University in NYC. The symposium will focus on Site Excellence in Clinical Research. The program follows:

**Friday, September 24, 2010**
Panel 1: Is your site good enough to get certified?
Panel 2: NCI Designated Cancer Centers
Panel 3: Information Technology Compliant Centers: Achieving Part 11 Compliance

**Saturday, September 25, 2010**
"Ask the FDA"
"FDA Final Guidance"

We received an overwhelmingly positive response to the 2009 symposium session that included a FDA panel discussion with audience interaction. Several attendees requested future sessions with the FDA and we had many requests to include perspectives from Drugs and Biologics, as well as, Device. This year's panel will include FDA inspectors or directors from thedrug (CDER), device (CDRH), and biologics (CBER) divisions. Members of the research community are welcome to pose questions at the event or send them in advance during the registration process.

The final event for the 2010 year will be on the evening of October 7th when Beth Israel Hospital Center hosts "Investigator-Initiated Research." The presentation will feature experts from both academia and industry and provide a comprehensive overview of best practices for conducting investigator-initiated research studies.
Marketing Committee

The Marketing Committee is responsible for obtaining sponsorship, coordinating social events, and updating promotional materials. This year the Board decided to introduce a new way of sponsorship called the Platinum. This type of sponsorship supports the chapter for the entire year instead of specific events. We are excited to report our first Platinum sponsor is Aerotek.

The Spring Networking/Job Fair was a huge success. Sponsors were thrilled with the abundant number of guests eager to learn more about the company/institution and open positions. Guests were pleased with the variety of academic institutions and companies that were present. The Flatotel Hotel was the perfect venue for the event and the wonderful staff made the night even more memorable. The committee is hard at work planning the last event of 2010, the holiday networking party. The holiday networking party is scheduled for December 2nd. We are exploring many fun venues and continue to work on sponsorships for both the fall 2 day symposium and holiday party.

Hope to see you there!

The New York Metropolitan Chapter of ACRP is proud to present the

Fall 2010 Clinical Research Symposium:
SITE EXCELLENCE IN CLINICAL RESEARCH

Sponsored by Aerotek, NYU CTSI & NYCON CTSA Consortium

Friday September 24, 2010: 7:30am - 4:30pm
Saturday September 25, 2010: 8:30am - 1:15pm

NYU Langone Medical Center
550 1st Avenue New York, NY

Register Online: http://2010symposiumnymetro.eventbrite.com/

Speakers will include:
Keynote speaker: Henry Spotnitz, MD - Columbia University Medical Center

Day 1:
Panel I - Is Your Clinical Research Site Good Enough to Be Certified?
June Rae Merwin - Pfizer, Inc.
Marjorie Speers - AHRPP
Carol Fedor - Center for Clinical Research at University Hospitals
George Gasparis - Columbia University Medical Center IRB

Panel II - NCI Designated Cancer Centers
Edward P. Gelmann - Columbia University Medical Center
Maryann Kral - Columbia University Medical Center
Linda K. Weiss - NCI

Panel III - Information Technology Compliant Centers: Achieving Part 11 Compliance
Victoria Spendel - Cincinnati Children's Hospital Medical Center
Lisa Weiss - Shire Pharmaceuticals
Jaime Lucove - Allscripts
Jules T. Mitchell - Target Health Inc.

Day 2:
Panel 1 - Ask the FDA
Michael E. Marcarelli - FDA
Constance Cullity - FDA
Panel II - NCI Designated Cancer Centers
Edward P. Gelmann - Columbia University Medical Center
Maryann Kral - Columbia University Medical Center
Linda K. Weiss - NCI

Workshop - FDA Final Guidance
Liz Wool - CMT QDQuality Training & Solutions

BRIEF PROGRAM DESCRIPTION: The two day event will emphasize how to obtain excellence in clinical research and showcase best practices for implementation within regulation. The fall symposium offers panel discussions that will offer the perspectives of regulatory professionals, Information Technology and Data Integrity professionals, research administrators, academic sites, industry sponsors, and the FDA. This educational opportunity will expand your knowledge of the current trends in conducting clinical research and provide critical discussion on the advancement of research and best practices.

PROGRAM OBJECTIVES:
Day 1:
1. Identify techniques to effectively manage clinical research
2. Learn to implement best practices in clinical research
3. Understand the requirements and potential benefits of AAHRPP certification
4. Evaluate methods for protecting patient health information and ensuring data compliance

Day 2:
1. Clarify FDA device and drug processes for clinical research oversight
2. Comprehend regulations and clarify investigator and site responsibilities in clinical research

SCHEDULE:
Day 1:
7:30am - 8:00am Registration and Breakfast
8:00am - 8:15am Address from the Board of Trustees
8:15am - 9:00am Keynote Speaker
9:00am - 11:00am Panel I: Is Your Clinical Research Site Good Enough to Be Certified?
11:00am - 11:30pm Break
11:30am - 1:30pm Panel II: NCI Designated Cancer Centers
1:30pm - 2:30pm Lunch
2:30pm - 4:30pm Panel III: Information Technology Compliant Centers: Achieving Part 11 Compliance

Day 2:
8:30am - 9:00am Registration and Breakfast
9:00am - 11:00am Ask the FDA
11:00am - 11:15am Break
11:15am - 1:15pm FDA Final Guidance

TARGET AUDIENCE: Clinical Research Professionals including CRAs, CRCs, and others in the New York Metropolitan and surrounding areas

COST:
Day 1: NY Metro ACRP Chapter members - $75
Day 1: Non-members - $100
Day 2: NY Metro ACRP Chapter members - $75
Day 2: Non-members - $100
Day 1 and Day 2: NY Metro ACRP Chapter members - $125
Day 1 and Day 2: Non-members - $175

Attendees who want contact hours must complete an evaluation. When registering for the event you will pay for the event only. The NY Metro Chapter will be paying for contact hours for Certified Chapter members who want contact hours for this event. Chapter Members who are not Certified and Global ACRP Members can purchase contact hours separately through ACRP Global. There will be a link on the ACRP NY Metro website (http://www.acrpnet.org/nymetro) to purchase contact hours for this event.

CANCELLATION AND REFUND POLICY: Full refund will be given prior to September 10th, 2010.

CONTACT HOURS: Contact hours have been applied for through ACRP.
Communications Committee

The Communications Committee is always looking for interested members to become more involved. The committee is responsible for sending out all chapter communications, including the monthly job boards and quarterly newsletters.

Any comments or suggestions regarding our chapter newsletters and job board are also appreciated. If you would like to become involved, please send an email to vl2126@columbia.edu.

Membership & Retention Committee

Welcome to our new and renewing Chapter Members:

Karen Chu  Michael Fusilero  Ronald Harris  
Brandy Haydel  Irit Hillman  James Kelly  
Sonia Kleiner-Arje  Khyati Mehta  Nicola O'Connor Moore  
Maria Petrillo-Myers  Elena Reynoso  Carlotta Rodriguez  
Caren Van Geyzel  Mary Ward  Kristi Womack

Chapter 2010 Calendar

September 24 & 25
2nd Annual Clinical Research Symposium
Registration is Open

October 7th
Investigator Initiated Studies
Registration is Open

December 2nd
Holiday Networking Party
Save the Date

Sponsorship Opportunities

Corporations, recruiters, or institutions interested in sponsorship of any of the 2010 events, or advertising open positions on the job board should contact the Chair of the Marketing Committee, Rachael Yoo at ry2203@columbia.edu. We have several available levels of corporate sponsorship.