NY Metropolitan ACRP Chapter
Winter Newsletter
January 2011

President’s Message - Lyn Goldsmith

The last two years as president of the New York Metropolitan Chapter has been a challenge and a delight. Looking back on my past New Year's resolutions for the chapter (Winter 2010 issue), most of my 2010 resolutions for the chapter were met: the chapter membership continues to grow, our first two day symposium was a real success, and the 2nd Spring Job Fair and Networking Party grew and was very well attended and productive for so many of our members and for all of the vendors. We also initiated the Job Board and have received great feedback from advertisers. The growth of our committees is the only resolution that was not fully realized. We have a steady, active membership and I hope many more of you volunteer to become a member of one of our committees. New committee chairs, elected board members, and committee volunteers always bring a breath of fresh air and creative energy and new ideas. Committee participation is great fun and can enhance your networking opportunities and is the best way to learn about the chapter and perhaps step up into a Chair position, or run for elected office.

The most significant change of the last two years has been the growth of the board. The Marketing and Communications committee was split into two separate committees, adding another Chair on the board. Rachael Yoo as Marketing Chair was able to find fantastic venues for our networking events, and Vanessa Laroche is doing an amazing job putting out the Newsletter and the Job Board. The Education Committee also added another Chair for shared leadership of this committee. Endless thanks to Erika Stevens and Halley Rogers, who manage to come up with program ideas, speakers and venues for all our educational events. Finally, new positions for members-at-Large were created. Rita Hoard, Le Dich, and Ann Marshack have been hugely helpful to all the Committee Chairs and the rest of the board.

Before I sign off, I want to thank three of our founding members, Janet Holwell (first chapter President and now current president) and Lisette Gonzalez (second chapter President, current treasurer, and now president-elect), and Jun Loquere (beloved Membership Chair) for their commitment and dedication and almost daily support of the chapter. Their steadfast leadership has been invaluable.

Without doubt, the chapter will continue to grow and prosper, and offer the best educational and networking events in New York metropolitan area. Best wishes to you and your families for 2011.

Lyn Goldsmith
On Friday, September 24th and Saturday, September 25th the NY Metropolitan Chapter held its second annual clinical research symposium at New York University. This event titled, "Site Excellence in Clinical Research" hosted 109 attendees and featured 15 speakers focuses on best practices in clinical research. The chapter offered free contact hours to certified members for this two day event. The keynote speaker, Dr. Henry Spotnitz, addressed the process for establishing research programs and panel discussions addressed Part 11 compliance, Accreditation and NCI designated cancer centers. The second day featured a presentation and Q&A from the FDA focusing on device and drug studies and an examination of the 2009 FDA Final Guidance on Investigator Responsibilities.

On October 7th, Beth Israel Hospital hosted a presentation on "Investigator Initiated Research". The focus of the discussion illustrated Industry supported Investigator Initiated Research (IIR), IIR in Academic Medical Centers (AMC), and National Institutes of Health (NIH) supported IIR. Individual presentations from Michael Lockshin, MD of Hospital for Special Surgery, Michael Argenziano, MD of Columbia University and Cynthia Barbitsch, Rph. of Pfizer were followed by a panel discussion and Q&A.

Our first educational event in 2011 will take place on Thursday, February 3rd at the Hospital for Special Surgery in New York City. This program will address "The Patient’s Perspective on Clinical Research." The event will include presentations from patients who were enrolled in clinical research trials to help to educate research professionals on what it is like on the other side of the consent form. The speakers will be provided by The Center for Information & Study on Clinical Research (CISCRP). We hope to see you there!

A Message from ACRP Global

The latest Readership Survey for The Monitor has launched. Nearly 475 people have completed the survey so far, but we need many more to make this a truly representative sample of our members.

If you haven’t already jumped in, please take a few minutes when you can to visit and complete the survey and encourage your colleagues to participate, as well!

Go to: http://www.zoomerang.com/Survey/WEB22BNRJ8XPB/
Marketing Committee

The Marketing Committee is responsible for obtaining sponsorship, coordinating social events, and updating promotional materials. The Board decided to continue seeking sponsorship for Platinum sponsorship, along with specific event support. The Platinum sponsorship supports the chapter for the entire year instead of specific events.

This year the Winter Holiday Networking was held at Sagaponack on December 2, Thursday. The quaint venue that reminded me of a secret restaurant in the Hamptons was the perfect place to host the intimate holiday affair. The attendees were happy with the opportunity to mingle with new contacts as well as reconnect with old friends. The food, drinks, and service was exceptional.

I am excited for 2011 and look forward to working hard with a new committee volunteers. We are committed in making this year even more memorable than last year.

The New York Metropolitan Chapter presents:

Patient’s Perspective on Clinical Research

February 3rd, 2011, 6:00PM – 8:30PM

Hospital for Special Surgery
535 East 70th Street, New York, NY

Program Description: This program will address the topic of clinical research from a patient’s perspective. The event will include presentations from patients who were enrolled in clinical research trials to help to educate research professionals on what it is like on the other side of the consent form.

Speakers provided by
The Center for Information & Study on Clinical Research (CISCRP)

Click to Register Now

Contact Hours have been applied for through ACRP

Check out our website at http://www.acrpnnet.org/nymetro
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:

Jakey Patwari  Tejal Vyas  Margaret Corvalan  
Peer Angione  Bogdana Dikovyska  Lihi Brocke  
Leandro Maranan  Susan Glick  Theresa Jacob  
Marlene Kern  Nelli Savkina  Alice Mercado  Eloise Heacock  
Oleg Lavrukhin  Elizabeth Jett  Sherif Ibrahim  Amelyn  
Rodriguez  Darleen Vecchio  Tu-Anh Vakili  Nissa Perry  
Joseph Reaume  Nicole Peccerelli  Margaret Andrew  
Dina Monte  Lois Mannon  Sharon Goldberg  
Kimberly Byrnes  Audrey Ades  Suzanne House  Jeanne Walker  
Jo-Ann Lee  Patricia Parry  Sabine Sonnleitner  Kerstin Albus  
Veronica Whalen  Faye Safavi  Mary Marks  Sarah Capello  
Kristen D’Amore  Pankaj Patel  
Denise Rushworth  Amelia Sherr  Deanna Hunt  Sally South  
Jenny Figueroa  Erin Brennan  Arsh-Joey Sianan  Sarah Jones

Aerotek Scientific Job Board

Aerotek is a leading employment agency providing technical, professional and industrial recruiting and staffing services. Aerotek has a long history of customized recruiting and placement solutions. Aerotek continually places best candidates at all levels of skill and expertise. Available Opportunity:

Clinical Research Nurse
Job Location: New Haven, CT
Employment Status: Full-time
Reporting to: Senior Clinical Research Nurse

Summary: The Clinical Research Nurse will be responsible for the day-to-day activities with the implementation and conduct of clinical studies. The position is a rewarding and challenging opportunity to use all your clinical and interpersonal skills as a Clinical Research Nurse coordinating cutting edge research along with neurologists and neuroscientists.

Scope & Impact: This position requires frequent close interactions with subjects, physicians and other staff members. Complete, accurate and timely reporting of data is essential.

Major Responsibilities:
- Must possess a detailed understanding of the study protocol and study consent forms
- Develops and maintains source documents and tracking logs relevant to the imaging study
- Participates in study initiation and close-out process
- Completes the study Case Report Form (CRF)
- Responsible for recruiting and scheduling of study participants, tracking the participant’s visits and projected dates of return as well as overseeing all data management within the study
- Completes the consenting process and inclusion/exclusion criteria to determine eligibility of study participants
Completes study visit activities including EKGs, laboratory samples, adverse event assessments, dispensing of thyroid blockade, concomitant medication review, neuropsychological assessments, and vital signs.

Completes follow up activities with both the site and the participant after the participant has departed from the facility.

Familiar with Good Clinical Practices (GCP) complies with all company Standard Operating Procedures (SOP).

Communicates all protocol violations, deviations and any study results that are not within normal ranges to the PI and/or the Senior Clinical Research Nurse.

Responsible for study medication accounting, dispensing and destruction as required by studies and procedures.

Works collaboratively with other study coordinators and sites.

Assists with lumbar punctures arterial lines, starts and maintains intravenous study medication.

Additional responsibilities to be delegated as deemed necessary by supervisor.

**Qualifications:**

- Current registered nurse license.
- Bachelor’s Degree &/or equivalent experience in a related field.
- Knowledge of Good Clinical Practices (GCP) and other Regulations.
- Able to multi task in fast paced environment.
- BLS and/or ACLS.
- BSN preferred, RN, with a BS ok. (Physician Assistant).
- Good amount of recent clinical experience: heavy clinical research (ONCO/Cardio/CNS) - at least 3 years.
- 50% patients, 50% going through paperwork.
- Participate in patient recruitment.
- Work with Excel.
- Trials that they will manage: will be working on 5+ trials at any given time.
- EDC experience (Inform, Medidata Rave).
- Microsoft Office, WORD, EXCEL, and Outlook.

For more information regarding any of these postings, contact:

Sarah Jones, CIR
Email: sajones@aerotek.com

**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.