IT'S OUR CHAPTER'S TENTH ANNIVERSARY!

PRESIDENT'S MESSAGE
Lisette Gonzalez, CCRA

I would like to welcome you to our Fall 2013 newsletter. The chapter has been very busy since the last newsletter.

ACRP Global paved the way for the chapters to hold local Certification Examination Classroom Prep Courses. There was a very short lead time to hold the class while ensuring the attendees had enough time to determine in what areas they needed to focus their study efforts before the September exam. Our chapter and the Northern California Chapter jumped at the opportunity to be able to provide the prep course to our respective members and clinical research community. It was a surprise to find out that we both chose the same date to hold the prep course, Saturday, July 27th, and as a result combined our efforts in the preparations for the first chapter-held prep course. It was a great cross-country collaboration. Both events were very successful. The NY Metropolitan Chapter would like to acknowledge the support we received from Lenox Hill Hospital and the Feinstein Institute of the North Shore-LIJ Health System, whereby they provided the venues and catering. Attendees had the opportunity to attend either in New York City with the trainer onsite or via interactive videocast from Manhasset, LI. A total of 26 CRC's and CRA's, hailing from NY, NJ, CT, PA, MO and Washington DC were in attendance. NY Metropolitan Chapter Immediate Past-President, Janet Holwell, presented the course. It was very exciting to be able to provide this educational opportunity to our chapter members and other clinical research professionals wanting to take the step toward certification. We are looking forward to hear how everyone does after they take their exam. Pictures from these and other past events will be posted on the Past Chapter Events page of our website.

The first 2014 certification exam will take place in March. A decision has not yet been made whether we will hold a prep course prior to that exam. Please send us an email at NYMetroACRP@gmail.com and let us know if you are interested in attending a prep course or your institution/company is interested in sponsoring one in January or early-February 2014. Be sure to include "Winter 2014 Prep Class" in the subject line of your email.

The Education Committee is in the homestretch to our 5th Annual Fall Symposium. This year’s topic is "Crisis Management in Clinical Research Setting." The full-day Fall symposium will take place on September 20th and we will be returning to Pfizer Headquarters. Please take a look at the flyer below for a description of the symposium, the agenda with a list of our speakers and a brief description of each of the three panels. We would like to thank our exhibitors for their support of this very important program. They are also listed below.

Our final educational event will take place on October 30, 2013 and will be held at the NYU College of Dentistry in New York City, NY. Dr Greg Koski, President of the
Alliance for Clinical Research Excellence and Safety (ACRES) in Massachusetts, will be our speaker that evening. Dr. Koski topic is titled “With All Good Intentions: Has Ethical Review of Human Research Gone Rogue?” Dr Koski will address current challenges facing our clinical research system for ethical review, including the concerns raised by the stalled ANPRM and the major pushback from the research community, both social science and bio-medical science sides. Dr. Koski will argue that it is time for a major overhaul of a system that has become more of a burden than a blessing. We would like acknowledge that the NYU College of Dentistry’s Masters in Clinical Research Program will be supporting this event by providing the venue and supporting the catering.

Our 10th Annual Holiday Networking Party that will take place on Thursday, December 5th will end the 10th Anniversary celebrations for 2013. We hope to have all of our past presidents in attendance that night. The location will be the 8th Floor Cafe at Saks Fifth Avenue once again but the event space will have a new look due to ongoing renovations to make it even better than last year.

Be sure to check the Upcoming Events page of on our website for additional information on all of our 2013 events.

I look forward to see you at the Fall Symposium at Pfizer on September 20th!

Best regards,
Lisette

UPCOMING CHAPTER EVENT

The New York Metropolitan Chapter of ACRP cordially invites you to attend our

5th Annual Clinical Research Symposium: Crisis Management in Clinical Research

Featuring keynote speaker:
Gregg Fromell, M.D.

Friday, September 20, 2013
8:15AM - 4:45PM
NYU Langone Medical Center
Pfizer Headquarters
235 East 42nd Street
New York, NY 10019

And speakers from:
Columbia University Medical Center, Ernst & Young, Mayo Clinic, Medtronic, Memorial Sloan Kettering Cancer Center, Mount Sinai School of Medicine, Parke-Davis (now a subsidiary of Pfizer) and Ropes & Gray LLP

EVENT DESCRIPTION: This symposium aims to look at the anatomy of dealing with a crisis or any major threat to a clinical research company or organization and how to mitigate those risks, recover from the new challenges it introduces, and learn from the experiences of others in the field. The theme this year was chosen in recognition of the many challenges that our research community faces, some of which may be self-imposed while others may be true acts of nature.

REGISTER NOW FOR EARLY BIRD RATES!
Early bird ends August 15th: $100 NYM Chapter / $125 Non-NYM Chapter
After August 15th: $125 NYM Chapter / $150 Non-NYM Chapter

At the door: $200 — No refunds after August 15th
PHOTO ID REQUIRED FOR ENTRY

For more information or to register for this event, visit www.NYMetroACRP2013Symposium.eventbrite.com, send us an email at nymetroacr@gmail.com or contact Lisette Gonzalez, CCRA at (917) 881-4295
5th Annual Clinical Research Symposium: 
Crisis Management in Clinical Research

Friday, September 20, 2013
Pfizer Headquarters - 235 East 42nd Street, New York, NY

8:15am – 9:00am Registration and Breakfast
9:00am – 9:20am Welcome from Chapter and Global
9:20am – 10:10am Keynote Address
Dr. Gregg Fromell, Vice President of Science Operations and Transformation for the Office of Science and Research (OSA) NYU Langone Medical Center

10:10am – 12:00pm Panel I: Planning and Prevention
Peggy Fay and Sheril Madrid, Medtronic
Erik Decker, Columbia University Medical Center
Jacob Neufeld, Memorial Sloan-Kettering Cancer Center

12:00pm – 1:00pm Lunch

1:00pm – 2:50pm Panel II: Crisis Management: On the Front Lines
Melissa Churi, Ernst & Young
Lori Jennex, Mount Sinai School of Medicine
Dr. William Quick, Formerly of Parke Davis (now owned by Pfizer)

2:50pm – 3:00pm Break

3:00pm – 4:50pm Panel III: Security and Legal Issues
Mark Barnes, Ropes and Gray
Li: Wool, IQ Quality & Training Solutions, BKG
Dr. Muhammad Heraliah, Mayo Clinic

This Event is Pending Approval of 6.5 Contact Hours

5th Annual Clinical Research Symposium: 
Crisis Management in Clinical Research

Friday, September 20, 2013
Pfizer Headquarters - 235 East 42nd Street, New York, NY

PANEL DESCRIPTIONS

Panel I: Planning and Prevention
This panel highlights strategies to prevent a crisis from happening, identifies procedures for implementation and provides strategies to reduce impact within research organizations. Speakers in the panel implemented robotic information security policies and emergency management programs into their research operations. Industry presenters will describe strategies to minimize risk in site selection.

Panel II: Crisis Management: On the Front Lines
This panel provides first hand accounts from those who experienced a “crisis” that impacted research operations. One speaker will share experience with a serious data breach. The second presentation addresses managing the public and federal response to the revelation of an unknown serious adverse effect of a drug post-FDA approval. Finally, the third speaker provides insight in helping companies and institutions that are in the midst of managing a crisis situation.

Panel III: Security and Legal Issues
This panel focuses on the potential legal ramifications of a crisis, as well as, the development corrective and preventive action plans. The audience learn processes for identifying a perceived threat to reputation/operations and ways to examine current business practices.
for a chance to WIN a prize at our
5th Annual Clinical Research Symposium
(you must be present at the symposium to win)

UPCOMING CHAPTER EVENT

The New York Metropolitan Chapter of ACRP presents:

With All Good Intentions: Has Ethical Review of Human Subjects Research Gone Rogue?

Wednesday, October 30, 2013
6:00 PM - 8:30 PM
6PM - 7PM Networking/Business Meeting
7PM - 8:30PM Educational Program
NYU College of Dentistry
345 East 24th Street
6th Floor, Room 6012
New York, NY 10010

Presented by:
Greg Koski, M.D.
President and Co-founder, Alliance for Clinical Research Excellence and Safety (ACRES)
Associate Professor of Anesthesiology, Massachusetts General Hospital, Harvard Medical School

EVENT DESCRIPTION: This session will address current challenges facing our clinical research system for ethical review, including the concerns raised by the stalled ANPRM and the major pushback from the research community, both social science and bio-medical science sides. Dr. Koski will argue that it is time for a major overhaul of a system that has become more of a burden than a blessing.

EVENT COST: This event is FREE for NY Metropolitan Chapter members and employees of NYU College of Dentistry, NYU Langone Medical Center, NYU School of Medicine and Bloomsburg Center for Clinical Research (with valid ID at registration) and $25 for non-chapter members. 1.5 contact hours are pending approval from ACRP Global. Contact hours can be purchased at www.acrmnj.org before or up to one week after the event.

Click here for more information on our Bring a Guest Campaign.

A special thanks to the NYU College of Dentistry’s Masters of Clinical Research program for hosting this event.

For more information or to register for this event, visit
www.NYMetACRP/2013October30.eventbrite.com, send us an email at
nymetacrp@gmail.com or contact Llorente Gonzalez, CCRP at (917) 881-4295
PAST CHAPTER EVENTS

June 6, 2013: 10th Annual Spring Networking Party
We would like to thank everyone who attended this year's annual Spring Networking Party at the Manhattan Club at Rosie O'Grady's on June 6, 2013. Once again, we had a wonderful turnout and enjoyed a memorable night filled with excellent food, conversation and fun games.

Congratulations to our raffle prize winner, Keith Win, and our icebreaker winners, Lisa Kim, Ellen Huang, Maria Teresa Viggiani, Vishal Patel, Sonita Gafary and Cerdi Beltre.

Pictures from these and other past events will be posted on the Past Chapter Events page of our website.

I am sure many of you attended and remember our March 20, 2012 education event that was held at Lenox Hill Hospital (North Shore- LIJ Health System) titled, "HeLa, Henrietta Lacks and the Laws and Ethics of Tissue Banking". If you didn't attend, I am sorry to say you missed an excellent presentation and discussion on current and proposed biobanking regulations and ethical questions raised by the best-selling book "The Immortal Life of Henrietta Lacks". However, the topic is back in the news!

On August 7, 2013, Malcom Ritter, Science Writer for the Associated Press, published an article titled "Feds, Family Reach Deal on Use of DNA Information". Two descendents of Ms. Lacks will sit on a 6 member panel who will review proposals to sequence DNA from cells derived from her tumor or use DNA profiles from those cells in their research. Some of you may have seen the article in your local paper, but I suggest you visit the link provided because your local newspaper may have edited out several paragraphs as mine did. Also, if you haven't read the book yet, I highly recommend it.

Lisette Gonzalez, CCRA
UPCOMING WEBINARS:

Tuesday September 10, 2013 1:00pm CDT
Clinical Research Coordinator On-boarding: Current Gold Standards for Industry
Sponsored by Forte Research Systems, Inc.

Tuesday September 17, 2013 11:00am - 12:30pm
That Awkward Stage: Transitioning from Paper Trial Master File to eTMF
Sponsored by DIA in cooperation with NextDocs

PRE-RECORDED WEBINARS:

When PIs Come a' Knockin': Everything Investigators Want to Know but are Afraid to Ask
Presented by Office for Human Research Protections (OHRP)
Handouts in PDF format
Transcript in PDF format

Understanding Major Regulatory Change
Sponsored by Appian

Clinical Trials in Asia: Opening Up to the World
Sponsored by PPD

COMPLIMENTARY WHITEPAPERS:

ACRP Offers White Paper on Informed Consent
Sponsored by ACRP

FDA FINAL GUIDELINE ISSUED
The FDA has issued the final guidance titled "Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring." Visit here to download a PDF of the guidance.

The New York Metropolitan Chapter of ACRP does not endorse nor profit from these advertisements or programs, but rather are providing a notification to its community for their own interest as part of its continuing initiative to promote education and opportunities in research.

to our new and returning chapter members!

We currently have 218 active members to date with 31 new members joining us in the last quarter. We would like to give a warm welcome to:

Eric Adegbite, Stephanie Augustine, Alex Buenaventura, John Bullington, Diane Cannon, Vasiliki Chantziara, Christie Lyn Costanza, Margaret DeFranco, Diane Dellilluna, Susan DeMocker, Ryan Gallagher, Christine Jumper, Emove Karonis, LaToya King, Jill Kleczko, Evelyn Koestenblatt, Dana Kuziw, Maria Marotta-Kollarus, Margaret Michel, Sara Miranda, Joanna Moreira, Ann Park, Matthew Paul, Eduardo Perez, Maria Petrillo-Myers, Pamela Pujols, Anita Roth, Fiona Sanders, Julie Statzel, Maria Symula and Barbara Wilkens.

For membership questions, email Jun Loquere at al2061@columbia.edu. You can also log on to www.acrpnet.org for ACRP and chapter membership applications.
WANT TO POST SOMETHING IN OUR NEWSLETTER OR JOB BOARD?

For information on placing advertisements in the quarterly newsletter or posting positions on the monthly Job Board, click here. You can also send your comments or suggestions to vl2126@columbia.edu.

SPONSORSHIP OPPORTUNITIES

The Marketing Committee is currently seeking sponsorship for our 2013 events. Corporations, recruiters, or institutions interested in sponsorship of any of our events should contact Janet Ellen Holwell at jholwell@aol.com or (718) 263-4160. We have several levels of corporate sponsorship available.

The Marketing Committee is always looking for volunteers. Any members interested in becoming more involved in the chapter should also contact Janet.