PRESIDENT'S MESSAGE

Erika Stevens, MA

As we welcome a new year, the ACRP NY Metropolitan Chapter continues to focus on providing education to our members while supporting the ACRP Global's mission to be the source for clinical research information. The 2015 program aligns with industry trends to provide further insight into the clinical research enterprise.

The following table illustrates recent data from the Center for Drug Evaluation and Research (CDER) highlighted issues of non-performance.
To eliminate issues of non-compliance in clinical research, our industry turns to Good Manufacturing Processes (GMP) for leading practice. The use of Corrective and Preventative Actions (CAPAs) for addressing adverse events, non-adherence, and unstable trends begins with the identifying of the root cause of the concern. Our education session led by Lee Truax-Bellows will provide further insight into this approach.

Other new chapter initiatives turn our attention to long-term chapter sustainability. Specifically, we are developing a Board book, Chapter Mentorship Program, and succession plan. The Board orientation stems from a need to provide Board background and orientation for new Board members. The focus is to prepare newcomers to serve as Chapter Board Members and highlighting the fundamentals of the ACRP NY Metropolitan Chapter. The end result should serve as a resource for on-boarding new Board members.

The focus around Chapter Mentorship Program is to provide support to new chapter members and provides further information for chapter activities. Pairing long-term chapter members with new members will enable opportunities for networking, professional development, and relevant chapter knowledge.

Finally, succession planning supports long-term chapter survival. Identifying and developing chapter members to fill key positions on the Board and sub-committees to increase chapter viability. Replacement of existing roles provides an opportunity for new talent and fresh ideas for the chapter. Fundamental succession planning supports chapter growth and development.

Best regards,

Erika

A MESSAGE FROM THE EDUCATION COMMITTEE

Thank you for sharing your ideas with us on event topics and chapter programs. We developed our entire educational program for the 2015 year based on your suggestions, and we think it will be one of our best years yet! The three most requested topics from the online surveys and paper evaluations were budgeting, non-compliance, and recruitment - which is precisely what we have in store for you this year.

We are always open to your suggestions, so please feel free to continue to send us your ideas or feedback at nymetroacrp@gmail.com.

Please have a look at our coming attractions listed below.

UPCOMING CHAPTER EVENTS
The New York Metropolitan Chapter of ACRP presents

Wednesday, March 18, 2015
6PM - 8:30PM
6PM - 7PM Networking/Business Meeting
7PM - 8:30PM Educational Program

Lenox Hill Hospital
North Shore/LIJ Health System
William Black Hall
130 East 77 Street
Theatre room -2nd floor
Achilles/Weisner
New York, NY 10075

Navigating The Winding Road of Root Cause Analysis
and
Corrective and Preventative Action Plans:
Make Them Work For You, Not Against You

Lee Truax-Bellows, MS, FNP, CCRA, RQAP-GCP
President and CEO
Norwich Clinical Research Associates Ltd. (NCRA)

Come Learn How to:
1) Define the principles of CAPA and RCA
2) Describe the steps and tools to develop CAPAs
3) Identify best practices for CAPA documentation and for resolution
4) Describe how lessons learned from individual CAPAs can lead to improvements in site or sponsor management

COST: This event is FREE for NY Metropolitan Chapter members and employees of Lenox Hill Hospital and North Shore/LIJ Health System (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 http://www.acrpnet.org before or up to two weeks after the event.
For more information or to register for this event, visit www.NYMetroACRPMarch18th2015.eventbrite.com, send us an email at

Facility space generously provided by North Shore/LIJ Health System. Catering generously provided by Infraredx
An Interactive Session on Clinical Research
Budget Development and Analysis

Tuesday, May 12, 2015  Christine Busby, AS, CPC
6:00—8:30 pm

6-7 PM  Networking/Business Meeting  Supervisor-Clinical Trials Pre-Award
7-8:30 PM  Educational Program  Dartmouth-Hitchcock Medical Center

Memorial Sloan Kettering Cancer Center
Zuckerman Research Center
Room 105
417 East 68th Street
New York, NY 10065

*Take the 6 train to 68th Street and walk east 3 blocks to First Ave.*

Please join us for an interactive discussion on clinical trial budget review and analysis to better understand the budgeting process and how it impacts your role.

**Event Objectives:**

- Describe the steps in analyzing and developing a clinical research budget
- Compare the differences between a site and industry sponsor budget, and discuss why this contrast is an important step
- Construct a clinical research budget based on a sample protocol

**COST:** This event is **FREE** for NY Metropolitan Chapter members and employees of Memorial Sloan Kettering Cancer Center (with valid ID at registration) and **$25** for non chapter members. Contact hours have been applied for through ACRP Global. Contact hours can be purchased at [http://www.acrpnet.org](http://www.acrpnet.org) before or up to two weeks after the event.

For more information or to register for this event, visit [http://NYMetroACRPMay12th2015.eventbrite.com](http://NYMetroACRPMay12th2015.eventbrite.com)

The facility space has been generously donated by Memorial Sloan Kettering Cancer Center.
The New York Metropolitan Chapter of ACRP Presents

Coming Attractions in 2015

An Interactive Session on Budget Development and Analysis

Tuesday, May 12, 2015
6:00—8:30 pm

Annual Clinical Research Symposium

Ethics in Clinical Research - New Challenges Facing Clinical Researchers Today and Tomorrow

Friday, September 25, 2015
8:00 am—4:30 pm

Recruitment in the Digital Age

Thursday, November 12, 2015
6:00—8:30 pm

This is a proposed schedule of educational activities
Please note that the dates are projected and may be subject to change
Clinical Research Programs

- Master’s Degree Program
- Certificate Program

Now accepting applications for Fall 2015 enrollment!
To learn more and apply, click here.
Clinical Skills Courses Available at the New York Simulation Center

Introduction to Vital Signs
One evening session, from 5:00 - 9:00pm • Register here.

Course Description: Vital Signs training includes temperature, pulse, respiration and blood pressure assessment. Successful performance of these assessments on 20 people and a successful passing grade is required. Materials are provided. Cost: $125.00

Introduction to Phlebotomy & EKG
Ten sessions bi-weekly, from 5:00 - 9:00pm • Register here.

Course Description: Students will be provided education in phlebotomy, EKG training and practice. The course is tailored to adult learning styles and promotes retention of key concepts through interactive lectures, multimedia presentations, group discussions and activities, and hands-on laboratory practice. Materials are included. Cost: $500.00

Location: The above courses are offered in the evenings and located at New York Simulation Center.

Target Audience: These courses are for non-nurse clinical research coordinators and study team personnel who may require proof of training to perform EKG, phlebotomy, and/or vital sign assessments under the direction of medically licensed personnel. Sponsored by NYU and BMCC/CUNY.

CHAPTER & MEMBER NEWS

The following NY Metro members will be presenting at the 2015 ACRP Global Conference and Exhibition in Salt Lake City, Utah:

Janet Ellen Holwell - Fundamentals of Clinical Research - April 22-23, 8:00 AM - 5:00 PM - Two-Day Workshop; co-presenter: Todd Almarez
Janet Ellen Holwell - Best Practices to Become a Preferred Site - W009 - April 24, 1:00 PM to 5:00 PM - ½ day Workshop; co-presenter: Deborah Rosenbaum

Janet Ellen Holwell - FDA Inspections: Handling the Consequences - Exploratory Learning Session - April 25, 2015, 8:30 AM - 10:30 AM; co-presenter: Glenda Guest

Carlotta M. Rodriguez - Top Five Pet Peeves: Impact, Management, and Potential Solutions - Exploratory Learning Session - April 26, 2015, 2:45 PM - 4:45 PM
Co-presenters are John Rowell, Director of Clinical Trials Office, LSU Health-Shreveport, Jill Petro, Associate Project Vendor Manager, Covance

Janet Ellen Holwell - Ensuring Success through Smarter Site Selection and Study Feasibility - April 27, 2015, 8:30 AM - 9:30 AM

Joy Jurnack - Partnership for an Informed Subject: A Research Nurse's Perspective as an advanced session - April 27, 2015, 8:30 AM - 9:30 AM
*Joy has also been selected to sit on the ACRP Global Ethics Committee

Cyndi Hahn is presenting with Soo Bang - CTTI Use of Central IRBs for Multicenter Clinical Trials - April 27, 2015, 8:30 AM - 9:30 AM

In addition to the above members presenting at the 2015 ACRP Global Conference and Exhibition the following members have indicated that they will be attending. Please reach out and network!

Eileen McCullagh
Joyce Ann Moran
Mee Lee Tom
Ruth J. Tenzler Stein

FREE EDUCATIONAL OPPORTUNITIES

UPCOMING WEBINARS

Recruiting Patients: 5 Proven Secrets to Social Media Success
March 12, 2015 at 12:00 pm CT
Presented by Forte Research Systems

Big Data's Role on Advancing RBM
March 18, 2015 at 12:00 pm EST
Presented by Society for Clinical Research Sites

Tackling the Unexpected Consequences of Clinical Trial Agreements
March 25, 2015 at 12:00 pm CT
Presented by Forte Research Systems

Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk
March 31, 2015 at 1:00 pm EST
Presented by PharmaVoice

PRE-RECORDED WEBINARS

Introduction to FDA's MedWatch Adverse Reporting Program
Presented by FDA Center for Drug Evaluation and Research
Effectively Managing Clinical Trial Receivables  
Presented by Forte Research Systems

Introduction to Post-Marketing Drug Safety Surveillance: Pharmacovigilance in FDA/CDER  
Presented by FDA Center for Drug Evaluation and Research

WHITEPAPERS

Cloud Computing that's Ready for Life Sciences

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.

Welcome!

to our new and returning chapter members!

We currently have 270 active members to date with 17 new and returning members joining us in the last quarter.

We would like to give a warm welcome to:

Demis Balamatsias, Marissa Ballesteros, Scott Baron, Claudine Davis, Lola Franco, Cynthia Howard, Nita Kurian, Lucy Lu, Elizabeth Molina, Matthew Paul, Michelle Rae, Catherine Schon, Rebeca Vasconcelos, Lorraine Vasi, Wendy Wasserman, Judith Weissman and Treena Williams.

For membership questions, email Jun Loquere at al2061@columbia.edu. You can also log on to www.acrpnnet.org for ACRP and chapter membership applications.

COMMUNICATIONS COMMITTEE UPDATE

Vanessa LaRoche, outgoing Communications Chair, eased the transition for new chair, Janet Holwell. We welcome a robust new team of volunteers: Carmita DePasquale, Barbra Fordyce, Marisa Kavanaugh-Hogans, Marlena Kern, Emily Maplebeck, Sumathy Sundarababu, MeeLee Tom, Sarah Tometen, Valerie Wilkins and Diana Wong. Special thanks to Lisette Gonzalez for her assistance.
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 jholwell@aol.com.

SPONSORSHIP OPPORTUNITIES

The Marketing Committee is currently seeking sponsorship for our upcoming 2015 events. Corporations, recruiters, or institutions interested in sponsorship of any of our events should contact Cyndi Hahn at chahn@nshs.edu or 516-562-2018. 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 Cyndi.