PRESIDENT'S MESSAGE

From the President, Christina Brennan, MD, MBA

Dear Fellow NY Metropolitan Chapter Members,

Clinical trials have become increasingly very costly for all and we are always looking for innovative ways to be more efficient in clinical trial design and the way we recruit patients to ultimately improve trial outcomes. Technology has become a big focus on how we can optimize these outcomes. Just to name a few; sponsors and sites are looking into patient centricity, data you can wear and mobile devices.

The approach of being patient centric requires us to hear things from the patient's perspective and have an open mind for innovation, where we can look to them for real world experiences. As patients are becoming more comfortable with using their mobile devices for everything from internet banking to shopping online, more are being utilized for sharing their health information, recruitment for clinical trials and improving their compliance with follow-ups. Expanding on the utilization of technology in clinical trials, data wearables is continuing to be a hot topic. It can allow the patients the flexibility to participate remotely, which can be very efficient and of value to the patient's time.

On another note, the Senate recently confirmed Dr. Scott Gottlieb as the commissioner of the FDA. This was met with a lot of controversy given his industry ties. Some are concerned whether he will be able to lead the FDA in an unbiased way. He is a physician and a cancer survivor who believes that FDA regulations hold back innovations. He has been a strong advocate for modernizing the critical path initiative and the more recently passed 21st Century Cures Act. Dr Gottlieb wants to improve the generic drug approval process. He wants to find ways to get those products to the market faster, which will provide more competition and will bring prices down. Dr. Gottlieb is also interested on combating the opioid addiction crisis in our nation. It should be interesting to watch how things will shake up.

Hope your year has been productive thus far. It was so nice to see many of you at our last two educational events hosted by our chapter. Looking forward to seeing you and some new faces at our fall offerings, our webinar on September 28th - Wearables and Big Data and our 9th Annual Symposium on Translational Medicine on October 27th.

Have a great summer,

Christina

EDUCATION COMMITTEE UPDATE

Two educational events down and two more to go!
Our next educational event is coming up right after the summer. On September 26th, David Blackman of PPD will present a webinar to our chapter on wearable devices and their role in the clinical research industry.

Last but not least, our 9th annual clinical research symposium will be held on Friday, October 27th. This full day event will take a more holistic look at "The clinical research landscape - a walk through the various research phases and complexities." Each phase of research presents its only set of challenges for each functional area. Experts in the field, representing both site and sponsor perspectives, will walk us through how each step differs as well as some of the skills, knowledge, and strategies that would be valuable to thrive in each environment.

We look forward to seeing you at a future event!

Halley Rogers
Chair, Education and Programs Committee

ACRP CONFERENCE AND EXPO

Here are some photos from the Certification Milestone and Inaugural Fellows Reception at the ACRP Conference and Expo.

CCRA 15 year milestone - 3 members of our chapter were honored - Lisette Gonzalez, Irene Neaman and Janet Holwell
CCRC 20 year milestone - Janet Holwell and Eileen McCullagh

3 of the 7 inaugural fellows - Janet Holwell, Deborah Rosenbaum and Barbara Schliebe (both on ACRP Academy Board)
FELLOWSHIP OF THE ACRP APPLICATIONS

Fellow of the Association of Clinical Research Professionals (FACRP) is a mark of distinction reserved for those who have made substantial contributions to ACRP and the industry at large. The Fellowship application process is open June 1 to August 31, 2017.

ACRP Members in good standing are eligible to apply for Fellowship when the following application requirements are met:

1. ACRP Members must be in good standing with ACRP for the previous five years, consecutively prior to submitting an application for Fellowship status.
2. Demonstrated evidence of active participation with the Association of Clinical Research Professionals;
3. Demonstrated evidence of significant contributions to the field of clinical research.

Please check the ACRP website to download an application and for further details.

UPCOMING CHAPTER EVENTS
ACRP Certification Exam Prep Classroom Course
Saturday, June 17, 2017
9:00 AM – 4:00 PM
Registration 8:30 – 9:00 AM

Trainer: Janet Ellen Holwell, CCRC, CCRA, FACRP, TIACR
Clinical Research Consultant

Location
Memorial Sloan Kettering Cancer Center
633 3rd Avenue, 3rd Floor Training Room
New York, NY 10016

Course Description:

The ACRP Certification Exam Preparation classroom course provides guidance on how to prepare for an ACRP Certification exam (e.g., CCRA®, CCRC®, and CFI®) to candidates eligible to take the exam.

The exam has changed in 2017. The certification programs are now aligned with the Clinical Trial Competency Framework developed by the Joint Task Force for Clinical Trial Competency. Knowledge areas reflect current practice as a monitor, study coordinator or investigator. The exam has been expanded from 5 relevant guidelines to 6 relevant guidelines: Declaration of Helsinki, ICH E2A, ICH E6, E8, E9 and now E11 Clinical Trials in Pediatric Population.

Familiarize yourself with the format of the exam, tackle example questions, and conduct a personal gap analysis to ensure you are fully primed to earn your ACRP Certification.

This classroom course was prepared by ACRP experts exclusively for Chapters to offer locally, and is taught by a trainer approved by ACRP to teach this course. It includes PowerPoint presentations/hand-out, interactive classroom exercises, discussions and question-and-answer sessions. No contact hours are offered.

Trainer Bio:

Janet E. Holwell, CCRC, CCRA, FACRP, TIACR

Ms. Holwell is an independent consultant specializing in maximizing excellence in GCP quality, compliance and training for both sites and industry. She began her career as a clinical research coordinator in academia over 30 years ago. Prior to transitioning to industry, she managed the clinical pharmacology unit in dermatology at NY Presbyterian Medical Center - Columbia University, overseeing all operations. She was an instructor in good clinical practice (GCP) and helped develop the first GCP program in an academic institution while at Columbia. She was an invited Lecturer for Columbia University School of Nursing’s post-graduate Course for Clinical Research Coordinators. Prior to her position in quality management as a Clinical Quality Lead with Pfizer, she held positions as a clinical research associate, site selection specialist, study manager with oversight of vendor CRAs, trainer and independent consultant. She has been an active member of the Association of Clinical Research Professionals (ACRP) since 1992, having served on the board of trustees, North American Council and various forums, including track chair for the site managers forum and co-chair of the CRA forum. She is a founding member, past president and presently an active board member of the New York Metropolitan Chapter of ACRP.

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Course Learning Objectives:

1. Be able to list and use the benefits of certification to drive their exam preparation efforts
2. Be familiar with the question-style and layout of ACRP’s Certification exams, including how to approach their multiple-choice format
3. Be able to identify and describe at least three (3) strategies for preparing for ACRP’s Certification exams
4. Be able to use and reference the six (6) relevant guidelines used to create the ACRP’s Certification exams:
   a. The Declaration of Helsinki
   b. ICH E7A—Safety Definitions
   c. ICH E6—Good Clinical Practice
   d. ICH E8—General Considerations for Clinical Trials
   e. ICH E9—Statistical Principles for Clinical Trials
   f. ICH E11—Clinical Trials in the Pediatric Population
5. Be able to assess their individual level of readiness by practicing exam questions based on the Detailed Content Outline (DCO) under training conditions (NOT exam conditions)

Agenda:

8:30AM     Registration Sign-in
9:00-9:15   Welcome and Introduction
9:15-11:00  Module 1: Objectives, Agenda, Introduction to Certification
11:00-11:15 Refreshment Break
11:15-12:15 Module 2: Overview of the 6 relevant guidelines
12:15-1:00PM Lunch provided
1:00-2:30  Module 2 Continued: Overview of the 6 relevant guidelines
2:30-2:45  Refreshment Break
2:45-3:45  Module 3: Practice Questions
3:45-4:00  Questions and Answers, Adjourn

Target Audience:
Eligible candidates for the CCRA®, CCRC®, and/or CPI® ACRP Certification Exam.

https://www.acrpnet.org/professional-development/certifications/

Questions About Certification Benefits, Requirements, and Preparation: www.acrpnet.org/certification

EVENT REGISTRATION closes Thursday, 15 June 2017, 11:59PM Eastern Time
Register NOW to ensure admission; PRE-REGISTRATION required
www.acrpnet.org/nymetro

NY Metro Chapter ACRP member $260
ACRP member $275
Non-member $380

Event registration information: Membership not required for online registration. Bring your email confirmation to the event. Please notify Event Manager of cancellation. No refunds or transfers. No contact hours offered.
Questions About ACRP Online Registration: chapters@acrpnet.org

Questions About This Classroom Course:
Janet Ellen Howell, CCRC, CCRA, FACRP, TIACR, Communications Chair, NY Metropolitan Chapter of ACRP, howellj24@juno.com or call 718-263-4150.

Event Manager for Cancellations: Lisette Gonzalez, CCRA, NY Metropolitan Chapter of ACRP, lgonzalez@phases2phaseconsulting.com or call 917-861-4295

Sponsorship Provided by

Memorial Sloan Kettering Cancer Center

Clinical Research Administration
Memorial Sloan Kettering Cancer Center
New York, NY 10016

Please see www.acrpnet.org/nymetro for more information about our Chapter and visit often to check on our upcoming 2017 events.

For those of you coming from out of town, click on the picture below for directions to the Memorial Sloan Kettering Cancer Center Training Room where the Prep Course will be held.

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Coming Attractions -- Save the Date
Registration opens soon

September 28:
Wearables and Big Data: The New Gold Standard for Clinical Trials

Speaker - David Blackman
Technology, Innovation and Partnerships Director
INFORMATION TECHNOLOGY
PPD
Venue: Webinar

October 27:
Fall Symposium: Translational Medicine - a Walk through the Research Phases and Complexities
Full Day Program with Multiple Speakers

December 7:
Holiday Networking Party

FREE EDUCATIONAL OPPORTUNITIES

UPCOMING WEBINARS

Electronic Health Records (EHR) as eSource in Clinical Trials
June 1, 2017 at 11:00 am EST
Presented by Business Review Webinars

How to Hire and Retain a Top Tier Clinical Research Team
June 7, 2017 at 1:00 pm EST
Presented by Forte Research Systems

How to Overcome the Latest Clinical Trials Logistics Challenges
June 8, 2017 at 10:00 am EST
Presented by Business Review Webinars
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.

We currently have 271 active members to date with 16 new and returning members joining us in the last quarter. We would like to give a warm welcome to:


For membership questions, email Jun Loquere at al2061@cumc.columbia.edu. You can also log on to www.acrpnnet.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 jholwell@aol.com.
SPONSORSHIP OPPORTUNITIES

The Marketing Committee would like to extend our most heartfelt thanks to the symposium exhibitors for supporting the event and engaging with our attendees. They include: Advanced Clinical, Aerotek, BRANY, Greenphire, and NYUMC. We also appreciated the donations from our in-kind sponsors CISCRP and CenterWatch.

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

Corporations, recruiters, or institutions interested in sponsorship of any of our events should contact Gabi Gaspard at gabig382@yahoo.com. We are currently seeking sponsorship for our upcoming 2017 events and have several levels of corporate sponsorship available.