From the President, Christina Brennan, MD, MBA Dear Fellow NY Metropolitan Chapter Members,

PRESIDENT'S MESSAGE

What will clinical trials look like in the future?

Telemedicine is reshaping clinical care, what will be its impact on clinical trials? Will clinical trials be impacted from this clinical pull or more of a technology push? Telemedicine is really another

of clinical trials enabled by technology. Some pharmaceutical companies are already piloting this approach. Travel time alone can be a factor for patient's participation into trials - perhaps this could be used in combination of some initial time for the patient on site for initial enrollment/intervention and some follow-up visits from home. It will be interesting to see how this will shape the future of clinical trials and gain further insights into the patient experience that will drive medical innovation. Hard to believe it is May already, the year is flying by. We had a great turn out at our first

kind of medical technology, the same principles of evaluation of costs and benefits need to be

educational event in March on project management in clinical research. Be sure to review ACRP's website for other opportunities that they offer learning more on this topic and how you can use it in your everyday work in clinical research. Hope to see you and some new faces at our next educational event at NYU to learn more on investigator initiated trials. Be Well. Christina

EDUCATION COMMITTEE UPDATE Our May 23rd event on Investigator Initiated Research (IIR) is almost here! If you have not

registered yet, registration is still open and we expect an excellent turnout at NYU to hear Dr.

Judith Hochman and Jacqueline Arciniega, MPH talk about how to fund, start, and conduct IIR.

After the summer we will host our last 2 events: an evening webinar in September on ICH Guidelines and a full day research symposium in late October on Career Development and Training in Clinical Research. We hope to see you later this month at NYU. Halley Rogers, MPH, CCRC

Chair, Education and Programs Committee

6:30 - 6:50 pm - Registration & Networking

7:00 - 8:30 pm - Educational Presentation and Q&A Target Audience: All Clinical Research Professionals.

6:50-7:00 pm-Chapter Meeting

Program Description:

How to Design and Conduct an Investigator Initiated Study Location: **NYU Langone Health**

Alumni Hall B, First Floor 550 First Ave. New York, NY 10016 Speakers: Judith S. Hochman, MD Harold Snyder Family Professor & Associate Director of Cardiology Senior Associate Dean for Clinical Sciences Co-Director, NYU-HHC Clinical & Translational Science Institute NYU School of Medicine Program Agenda:

Investigator Initiated Research (IIR) is a critical and unique area that provides an invaluable perspective on interventional research with human subjects. Please join us at NYU on May 23rd to learn from Dr. Judith Hochman, an experienced multicenter lead principal investigator, and Jacqueline Arciniega, an Administrative Director, to find out what it takes to fund, start and run an IIR. Upon completion of this course attendees should be able to: 1. Define key differences between Investigator Initiated vs. Sponsored Initiated Trials 2. Describe how to overcome challenges of the investigator becoming the sponsor of a trial: The PI perspective and Administrative Perspective 3. Evaluate how working together as a team can increase successful study conduct and oversight Registration Cost: \$0 Chapter Members / \$25 ACRP Members/ \$25 Non-Members. Register at Eventbrite. Contact hours: 1.5 Contact hours applied for through ACRP. Contact hours are complimentary for Chapter Members, \$15 for

obtain online certificate. Refund Policy: No refunds unless chapter cancels event.

ACRP members and \$30 for nonmembers. Membership not required for online registration of contact hours. To receive contact hours: Purchase contact hours on the NY Metro Chapter website, sign in at registration desk, and attend program. Log on to the ACRP website then "ACRP Learning Portal" to complete evaluation no later than 30 days following event and

JOIN THE NEW YORK METROPOLITAN CHAPTER OF **ACRP AND FLORENCE HEALTHCARE FOR A SPECIAL** NETWORKING EVENT Enjoy cocktails and passed hors d'oeuvres.

The evening will feature a special talk on

The Manhattan Club (at Rosie O'Grady's)

New York, NY 10019 Event Cost: \$25. Prior registration is required. Register at Eventbrite There are no Contact Hours for this event. Refund Policy: No refunds unless chapter cancels event.

Florencehc.com/eBinders

Registration

201 West 52nd Street

FlorenceTeam@florencehc.com

Space is limited!

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.

Trials in Pediatric Population.

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

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

The exam 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

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.

V3-13Mar2018

Course Learning Objectives: 1. Be able to list and use the benefits of certification to drive their exam preparation efforts 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 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 E2A—Safety Definitions ICH E6—Good Clinical Practice

Be able to assess their individual level of readiness by practicing exam questions based on the <u>Detailed</u>

Welcome and Introduction 9:00-9.15 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

8.30AM

Agenda:

3:45-4:00 Questions and Answers, Adjourn Target Audience: Eligible candidates for the CCRA®, CCRC®, ACRP- CP® and/or CPI® ACRP Certification Exam. Fall Certification Exam Cycle: September 10 - October 8, 2018. Application deadline: August 17, 2018. Early Bird Exam Registration: May 1, 2018 - June 15, 2018. Regular Registration: Starts June 16, 2018.

 d. ICH E8—General Considerations for Clinical Trials e. ICH E9-Statistical Principles for Clinical Trials ICH E11—Clinical Trials in the Pediatric Population

Registration Sign-in

Content Outline (DCO) under training conditions (NOT exam conditions)

\$325 Non-member 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. V3-13Mar2018 Questions About ACRP Online Registration: chapters@acrpnet.org

Janet Ellen Holwell, CCRC, CCRA, FACRP, TIACR, Communications Chair, NY Metropolitan Chapter of

622 W. 168th Street New York, NY 10032 Please see www.acrpnet.org/nymetro for more information about our Chapter and visit often to check on our upcoming 2018 events. For those of you coming from out of town, click on the picture below for directions to the Columbia University, Presbyterian Hospital (PH) 10 - 405A, where the Certification Prep Course will be held.

I was first inspired to become a doctor, but became interested in biomedical research as a sophomore in high school. I chose the field of Public Health because I wanted to be in a field that could have population level impact. I chose epidemiology because it is a data-driven, methods based, and systematic field. I was also drawn to epidemiology because I am able to work across many health-related areas and apply the skills I learned through my epi training. 2. Considering the length of time you have worked in research, can you speak about the evolution of research? Have you noticed a change in the way subjects are recruited, the involvement of industry sponsors, PI oversight, etc? I feel the biggest evolution in clinical research has been our ability to better understand, prevent and treat medical conditions. One big area I've seen the most advancement in is how we capture data across multiple study sites for a single study.

Can you tell the readers about how you chose your career path, namely what lead you to epidemiology?

these studies.

July 17, 2018 at 12:00 pm EST Presented by Kinetia ON DEMAND WEBINARS

Consistency Leads to Above the Curve Performance in Clinical Trials Presented by Business Review Webinars ARTICLES

Will the Technology Industry Take Control of the Clinical Trial Experience? Presented by Forte Research Systems

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.

The New York Metropolitan Chapter of ACRP does not endorse nor profit from these

Welcome/

We currently have 281 active members to date with 13 new members joining us in the last

quarter. We would like to give a warm welcome to:

Maddalena Mastrogiacomo

Irene Neaman

BOARD?

to our *new* and *returning* chapter members!

chapter members: Lisette Gonzalez Janet Holwell Jun Loquere

Jun Avelino Loquere Chair, Membership Committee

log on to www.acrpnet.org for ACRP and chapter membership applications.

For membership questions, email Jun Loquere at <u>al2061@cumc.columbia.edu</u>. You can also

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.

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 2018 events and have several levels of corporate sponsorship available.

applied. Clinical investigators will need to maintain their clinical perspective and scientific rigor, since these trials are driven by high technological advances and sponsored by those who provide it. These types of trials will become virtual sites or known as site less trials. It will bring trials out of the traditional brick and mortar and into the patient's homes. This is definitely a futuristic vision

Wednesday, May 23, 2018 6:30 - 8:30 pm

Jacqueline Arciniega, MPH Administrative Director, Office of Science and Research Project Director, Zoster Eye Disease Study (ZEDS) NYU Langone Health Refreshments are provided by Medix. Medix does not have any influence on the content of the presentation.

Level: Intermediate

Stay tuned to our Chapter website at Association of Clinical Research Professionals - New York Metropolitan Chapter. or send us an email at nymetroacrp@gmail.com.

"The Ethics of Reprogenetics" by Inmaculada de Melo-Martín, PhD. MS Tuesday, June 12, 2018 6:00pm-8:30pm 7-7:30 - Featured talk

Florence eBinders is the leading solution for simplifying and advancing clinical research. Trusted by more than 2,000 research teams around the world our only focus is equipping sites and sponsors with the best eRegulatory, eSource and contract management solutions.

CRP Certification Exam Prep Classroom Course Saturday, June 23, 2018

9:00 AM - 4:00 PM Registration 8:30 - 9:00 AM Trainer: Janet Ellen Holwell, CCRC, CCRA, FACRP, TIACR Clinical Research Consultant Location Columbia University - Irving Institute for Clinical and Translational Research 622 West 168th Street, Presbyterian Hospital (PH) 10 - 405 A New York, NY 10032 Course Description:

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

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

Questions About This Classroom Course:

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

Register NOW to ensure admission; PRE-REGISTRATION required www.acrpnet.org/nymetro Early Bird Pricing After June 4, 2018 Before June 4 2018 NY Metro Chapter ACRP member \$250 \$275 ACRP member \$275 \$300 \$300

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

EVENT REGISTRATION closes Thursday, 21 June 2018, 11:59PM Eastern Time

ACRP, jholwell@aol.com or call 718-263-4160. Event Manager for Cancellations: Lisette Gonzalez, CCRA, NY Metropolitan Chapter of ACRP, Igonzalez@phase2phaseconsulting.com or call 917-881-4295 Sponsorship Provided by IRVING INSTITUTE FOR clinical and translational research Ismael Castaneda, Research Manager Clinical Research Resource (CRR) Columbia University - Irving Institute for Clinical and Translational Research

This month's interview is with Jacqueline Arciniega, the Director of Strategic Initiatives and Programs at NYU Langone Medical Center's Office of Science and Research. Her experience in research, her Master's in Public Health from Columbia University, and her background as an epidemiologist make her an ideal speaker for an upcoming ACRP New York Metropolitan Chapter course later this month that she will be conducting with Dr Judith Hochman.

SPOTLIGHT on Research by Marisa Kavanaugh-Hogans, MPH, BSN, RN-BC, CRC

3. In regard to your upcoming program at NYU, "How to Design and Conduct an Investigator Initiated Study", what subjects do you hope to cover during your presentation on May 23? The program aims to help the audience understand the complexities around designing and conducting an investigator

initiated study. I hope that after the session the audience will take away the critical role clinical research professionals like CRA, CRCs, Project Managers, etc. play in helping throughout the entire design, implementation, and conduct of

FREE EDUCATIONAL OPPORTUNITIES UPCOMING WEBINARS

> Understanding, Achieving and Maintaining 21 CFR Part 11 Compliance May 15, 2018 at 1:00 pm EST Presented by Forte Research Systems

> > RBM - More Than Risk May 16, 2018 at 11:00 am EST Presented by Business Review Webinars

Optimizing Your Clinical Trial Performance through Metrics and Benchmarking May 23, 2018 at 11:00 am EST Presented by Forte Research Systems

Is Your Site Ready for eConsent?

Presented by Kinetiq Streamline Your Clinical Trial Workload with Effective Project Management Presented by Forte Research Systems

Prepare Your Site for Challenges in Gene Therapy Research

Chrystelle Bougault; and Angela Cartmell-McGlyn Also a big congratulations to the following members who have reached their 15-year milestone as

James Holahan; Michelle Pritikin; Sunita Paul; Susan Puleio; Marissa Barbieri; Fatiha Chabouni; Julton Tomanguillo Chumbe; Grace Chan; Melissa Ramgadoo; Michelle Yuan; Kristina Dushaj;

WANT TO POST SOMETHING IN OUR NEWSLETTER OR JOB

SPONSORSHIP OPPORTUNITIES

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

Study May 23, 2018 6:30 - 8:30 PM Summer Networking Event June 12, 2018 6:00 - 8:30 PM ACRP Certification

UPCOMING EVENTS

How to Design and Conduct an Investigator Initiated

Exam Prep Classroom Course June 23, 2018 9:00 AM - 4:00 PM 2018 Officers President Christina Brennan, MD, MBA

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Committee Chair Halley Rogers, MPH,

TIACR

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Membership & Retention

Nominations

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Committee Chair

Carlotta Rodriguez, MS, CIP, CHRC Member at Large Open VISIT OUR CHAPTER WEBSITE

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