PRESIDENT’S MESSAGE

From the President, Christina Brennan, MD, MBA

Dear Fellow NY Metropolitan Chapter Members,

What is a clinical trial? According to the NIH, it is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. There are 4 specific criteria that must be met in order to be defined as a clinical trial:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

The NIH is the largest federal funder of clinical trials in the United States. They rely on the public trust in scientific rigor, transparency, and ethical oversight. The NIH wants to support trials that investigate high priority questions and avoid duplicating previously conducted trials. They want to improve oversight and transparency. There are many trials that get completed but their results are never shared publicly. The NIH is sensitive to the time participants gave in these trials and there is an obligation to report and disseminate results in a timely fashion.

The policy change began to emerge in 2014, when NIH revised its definition of clinical trials. Then, last September, NIH announced more extensive requirements for all trials the agency funds. It mandated new training for trial staff as well as registration and results reporting on clinicaltrials.gov. Over the next few months the NIH will be providing updated information, tools and resources as a guidance to the definition of a clinical trial.

I hope you all had a great summer. Looking forward to seeing you and some new faces at our chapter fall offerings, our webinar on September 28th - Wearables and Big Data and our 9th Annual Symposium on Translational Medicine on October 27th. Save the date for our annual holiday party which will be held on December 7th, an event you don’t want to miss!

Kind regards,

Christina

EDUCATION COMMITTEE UPDATE

Two events down and two to go! Back by popular demand, we are pleased to provide another webinar series this year for you to easily access from your home or office. On Thursday, September 28th, David Blackman from PPD will host a session on wearable technology and its future and current applications in clinical trials. Whether you work on drug, device, or observational trials you will find something relevant in the presentation for you.

Then, last but not least, is our highly anticipated full day clinical research Symposium on Friday, October 27th. This year the venue will be the prestigious New York Genome Center in Manhattan. The topic this year is the Clinical Research Landscape: a walk through the different research phases and the skills and challenges unique to each one. To kick off the event this year, we are...
pleased to have two patient speakers who each have had experience with clinical trial participation and can provide something that we all stand to learn from. Please see the event flyer in this newsletter for further details on the speakers, objectives, and location details. We look forward to seeing you there.

Halley Rogers
Chair, Education and Programs Committee
Pharma for me was the fact that while Sankyo managed their Phase 3 studies via CROs, the individual Eyetch clinical teams managed the secondary monitoring, site payments and maintaining the Trial Master Files for their individual studies. My role was that of North American Study Manager with an amazing team of four in-house CRAs, a Study Coordinator and approximately 14 very experienced independent monitors who were site managers for the sites in the US and Canada. In addition, there was a separate team who handled the studies in the countries outside of the US and Canada. It was amazing to become exposed to all of the tasks that the CROs had handled in my past Phase 3 studies and work closely with the ex-US team so that we could ensure the timelines were met. I have been extremely fortunate to work with companies where I was exposed to a host of different responsibilities that helped me grow professionally. I always say that the experiences that I gained working at these three companies were priceless and may not have been possible in a very large company.

2. Can you tell the readers about Phase 2 Phase Consulting Inc. and what lead you to start the company?

When transitioning from Sankyo Pharma, I thought about becoming an independent clinical research professional, but after meeting with the teams at Eyetch Pharmaceuticals, I realized the opportunities for professional growth were too good to pass up. After the company was acquired and a decision was made to close Eyetch, I decided that the time was perfect to join the ranks of the independents. Being independent has allowed me the opportunity to work in new and different therapeutic areas.

3. Do you have any advice for research professionals who are considering venturing out to start their own businesses?

You definitely need to look at all of the additional financial reporting responsibilities to maintain your business and the additional expenses that may be incurred, e.g., how will you handle medical insurance, professional liability insurance and the additional social security payment (employer portion) and other employment and possibly corporation taxes, when evaluating whether becoming independent will fit your needs. It is extremely important to discuss your plans with your CPA, so that s/he can guide you in what are the financial considerations you need to keep in mind when you choose what type of business entity (LLC or Corporation or other) you will select. You should have a lawyer review your contracts to be sure that your business interests are protected. Before I chose incorporation, I spent time reading books about consulting, independent contracting and chatting with several friends who had already been working as an independent in clinical research. It may not be the best choice for everyone so I suggest that you reach out to people you know that are independent and ask questions. Another recommendation is to maintain your connections, network and attend industry conferences. I have been fortunate to have obtained all of my projects through referrals from former colleagues or managers. I once had a site contact me to monitor their investigator initiated Trial after I had completed monitoring a sponsor trial they conducted at their site. There are some CROs that will take on an independent monitor rather than requiring the monitor to become an employee of the CRO. You will also need to decide whether you want to commit yourself 100% to a single project or to work on multiple projects with different companies. If you choose the latter, you will need to be mindful of whether your contract language includes any limitations, e.g., therapeutic area or mechanism of action to name two possibilities. You don’t want to run into any conflicts of interest that may end up keeping you from working with the client in the future if it becomes known that you are in working on a competing product. Your lawyer will advise you of the potential issues with a contract prior to accepting a project. These are just some of the main items to consider when evaluating taking a new direction in working in clinical research.
Wearable Devices and Their Current Applications in Clinical Trials

Webinar Series
Thursday, September 28, 2017
6:30-8:15 pm

Presenter:
David Blackman
Senior Director of Business Innovation,
Corporate Development and Strategy
PPD

Program Description:
The use of wearable devices for the collection of health data has expanded beyond the healthcare setting and into the realm of clinical trials. Please join us as David Blackman of PPD presents on the current clinical trial applications of this wearable technology and where it will go in the future.

Upon completion of this Webcast, attendees should be able to:
1. Define wearable sensors and platforms for the patient.
2. Describe what’s driving the promise of remote patient data capture and the growth in wearable platform development.
3. Describe the future role of wearable devices in the healthcare and research setting

Agenda:
6:30-6:45 Welcome and Chapter Meeting
6:45-8:00 Educational Program
8:00-8:15 Q&A

Level: Intermediate

Cost: Complimentary for Chapter Members/$25 ACRP Members and Non-Members

Registration: Register at EventBrite. Webinar instructions will be sent to the user’s registration email closer to the event.

Contact hours: 1.5 Contact hours and CMEs have been applied for through ACRP. Membership is not required for online registration of contact hours.

Contact Hour Cost: Complimentary for Chapter Members/$15 ACRP Members/$30 Non-Members

To receive contact hours: Purchase the contact hours on the NY Metro Chapter website and attend the program. Between 1 and 30 days after attending the webcast, log on to the ACRP website, then click on your ACRP Learning Portal Quicklink to complete the evaluation and receive the online certificate.

Refund policy: No refunds unless the chapter cancels the event.
ACRP
The New York Metropolitan Chapter of ACRP presents our:

9th Annual Clinical Research Symposium:

The Clinical Research Landscape:
A Walk Through the Challenges and Complexities

Friday, October 27, 2017
8:30 am - 4:45 pm
NY Genome Center
101 Sixth Ave
New York, NY 10013
(btw. Grand St and Watts St.)

Program Description:
It is a rarity in the clinical research industry to spend your entire career in one position, one phase of research or even one therapeutic area. The knowledge and skills required for designing, conducting, reviewing or overseeing research programs across the various clinical trial phases are often unique and may require a different set of considerations. Please join us for a comprehensive overview by experts in the field of the nuances and challenges that you may encounter across the research spectrum, from early development to compassionate use to post-marketing.

Upon completion of this symposium, attendees should be able to:
1. Identify strategies that will make you successful as a clinical researcher in each phase of development.
2. Explain how conducting a phase 1 trial differs from a phase 2/3 trial.
3. Describe the nuances of compassionate use and expanded access research.
4. Identify the skills that you may need to transition from one phase to another.

Target Audience: All clinical research professionals.

Registration: EARLY BIRD RATES until Sept 29th: $100 NYM Chapter / $125 Non-NY Metro Chapter Members
After September 29th: $125 NYM Chapter / $150 Non-NYM Chapter
At the door: $200 — Check or credit card payments only.
No refunds after October 13th

For more information, send us an email at nymetrcr@gmail.com

Contact hours: 6.5 Contact hours have been applied for through ACRP. Membership is not required for online registration of contact hours. To receive contact hours: Purchase the contact hours, sign in at the registration desk, and attend the program. Log on to the ACRP website, http://www.acrnnet.org, then “ACRP Learning Portal” to complete the evaluation.
# 9th Annual Clinical Research Symposium:
The Clinical Research Landscape: 
* A Walk Through the Challenges and Complexities *

**Speaker List:**
* Keynote Speakers: TJ Sharpe and Jamie Troll *

Who better to set the tone for a full day analysis on the topic then the patients themselves? Thanks to CISCRR, this year we are fortunate to have two experienced and motivated patient speakers who have both participated in clinical trials.

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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>8:30-9:00 am</td>
<td>Registration and Breakfast</td>
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<td>9:00-9:10 am</td>
<td>Chapter Welcome</td>
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<tr>
<td>9:10-10:10 am</td>
<td>Keynote Address: TJ Sharpe, Jamie Troll</td>
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<td>10:10-10:20 am</td>
<td>Break</td>
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| 10:20 am—12:10 pm | Panel 1: Phase 1/First-in-Human Trials Dr. Scott Mellis (Regeneron)  
Jim Nissel (Tagove)  
Dr. Gualberto Perez (GCR Research) |
| 12:10—1:00 pm | Lunch                                       |
| 1:00—2:45 pm | Panel 2: Phase 2/3 Clinical Studies          |
|             | Diane Lewis-D’Agostino (Boehringer Ingelheim)  
Jillian Carrel (Accenture) |
| 2:45-3:00 pm | Break                                       |
| 3:00—4:45 pm | Panel 3: Managed Care Programs and Investigator-initiated Studies  
Peggy Schrammel (Parxel)  
Theresa Lukose (Columbia University Med Ctr)  
Mary Voehl Hirsch (Sanofi) |
ACRP
New York Metropolitan Chapter

The New York Metropolitan Chapter of ACRP presents our:

9th Annual Clinical Research Symposium:
The Clinical Research Landscape:
A Walk Through the Challenges and Complexities

Vendors

Advanced Clinical  Complion
BRANY          Florence Healthcare
CISCRP        Northwell Health

Please bring your business card or printed contact information for a chance to win one of our door prizes.
Florence Healthcare will be raffling off a $250 Southwest gift card.
FREE EDUCATIONAL OPPORTUNITIES

UPCOMING WEBINARS

Going Virtual: Evolving Real World Evidence Study Design for Speed, Flexibility & Lower Cost
September 19, 2017 at 11:00 am EST
Presented by Business Review Webinars

Best Practices for Ethical and Compliant Delegation of Authority at Your Research Institution
September 28, 2017 at 1:00 pm EST
Presented by Forte Research Systems

Proactively Manage Your Clinical Trial Risks
October 5, 2017 at 11:00 am EST
Presented by Business Review Webinars

Innovative Technology Solutions for Implementation of ICH E6(R2)
ON DEMAND WEBINARS

Implementing the New Common Rule - Practical Advice for Research Organizations
Presented by Kinetiq

Top 3 Challenges in Clinical Research and How to Address Them
Presented by Forte Research Systems

What Errors are Lurking in Your Trial Data?
Presented by Business Review Webinars

ARTICLES

The Professional Research Subject: Fact or Fiction?
Presented by Forte Research Systems

How to Start Effort Tracking at Your Clinical Research Site
Presented by Forte Research Systems

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 266 active members to date with 20 new and returning members joining us in the last quarter. We would like to give a warm welcome to:

Joanna Collado, Aileen Orpilla, Melany Signatovich, Mary Olson, Caroline Torres, Jeanne Walker, Yordak Salermo, Svitlana Shylman, Lorie Swain, Valerie Leung, John Fay, Gwendolyn Tan-Augenstein, Laura LaRosa, Patricia Krug, Rosio Ramos, Meredith Feinberg, Susan Fiore, Nancy Nahmias, George Zikos and Maria Teresa Minaya.

For membership questions, email Jun Loquere at al2061@cumc.columbia.edu. You can also log on to www.acrprnet.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

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.

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