

A NEWSLETTER
BRINGING YOU
THE LATEST
UPDATES FOR
THE GREATER
PHILADELPHIA
CHAPTER OF
ACRP

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Notes from the Chapter President...



Welcome to another edition of our Greater Philadelphia ACRP Chapter Newsletter. Nominations have been received and the 2011 Board Members have been decided.

Please join me in welcoming:

President — Jeff Collins

Secretary — Deidre Adore

Conference Chair — Gina Rothenberger

Dinner Meeting Chair — Katy Guarino

Communication Chair — Suzanne McCaffrey

Immediate Past President — Sandra DiGiambattista

Vice President — Jill Herring

Treasurer — Annette Bernstein

Membership Chair — Linda Cruz

Photographer — Linda Ubelacker

All new roles are effective January 1, 2011. I want to thank all of you who stepped up to the plate to continue delivering the quality educational programs and networking events our chapter is known for.

There are plenty of opportunities for volunteerism. Here are some examples:

- Sponsor an event venue or a meal
- Help plan next year's 2-Day Conference
- Become a speaker at a dinner meeting
- Lead an advertising campaign
- Write an article for our newsletter
- Run for a board position in 2012

Greater Philadelphia ACRP Chapter will recognize all volunteers and sponsors by documentation of involvement. All sponsors logos are displayed at our events. Contact us at acrp.greater.philly@gmail.com.

-Sandra DiGiambattista

UPCOMING MEETINGS

DINNER MEETINGS:

September 16

Use of Imaging in Clinical Trials
Dr. Rick Patt, RadMD
ECRI Institute Headquarters
Plymouth Meeting, PA

October 28

What to expect before, during, and after an FDA Audit
Mike Rashti, FDA Inspector

November 18

Clinical Research Coordinator Career Pathways
(Joint meeting between industry and academia)
Lankenau Hospital

December 2

Annual Networking Meeting

2-DAY EDUCATIONAL CONFERENCE:

May 12-13, 2011

The Hub at Cira Centre, Philadelphia, PA

MEMBERSHIP UPDATE

We are pleased to welcome 47 new members to our chapter!

Thank you for joining our exciting organization and growing our chapter to new horizons.

We look forward to meeting you at our fall events.

-Gina Rothenberger

	Jan-March	April-June	Total
New Members	23	24	47
Renewals	23	23	46

Greater Philadelphia Chapter of ACRP

By Neal Goldman

It was an idyllic setting, unlike any other conference I've attended. Small patches of wavelets briefly ruffled the glass-like surface of the early morning Delaware River. Ducks and ducklings swam slowly close to shore. Despite the setting outside, it was easy to get energized by the highly relevant and insightful presentations provided at the 2 Day Educational Conference "Tips, Tricks and Tools of the Clinical Research Trade" at the Lambertville Inn in Lambertville, NJ on May 6-7, 2010.

With over 80 attendees the first day, and over 60 the second, this well-attended event has become our signature event in just its second year. Each day featured presentations on topics of critical importance to everyone working in the clinical trials industry. That they were well received was evident because all were followed by extensive question and answer sessions.



Photo by Eva Pastor
Our venue, the Inn at Lambertville Station

Day 1

Communications Strategies for Clinical Research Professionals: Kathleen Dyer of Executive Outcomes Consulting gave us a fascinating exercise in Enneagrams. Kathleen taught participants about themselves and team members, and how to be more effective working with others.

Contract Negotiations and Financial Considerations for Independent CRAs: Maria Monshaw, CCRA, gave an overview of what it means to be an Independent CRA, including the differences between using a W-2 and 1099. She made participants aware of what is needed in order to not only see what goes into the final hourly wage we contract for, but then to leverage the contracts to help plan for the future.

Managing and Training Different Generations in the Workplace: Armand Spoto of Lernia presented a highly entertaining and vitally important example of how each generation, thinks, acts, and aspires to sometimes very different things. It is only through learning and appealing to what is important to each group that we will succeed in promoting our agenda (training, efficiency improvements, etc.).

Innovative Tools to Enhance Patient Recruitment: John Needham and Elizabeth Monech presented on a topic that is central to everything we do...solving the mystery of patient recruitment. They used a terrific metaphor on how to find them: Fish where the fish are, Know what they are biting on – Get the patients to understand the value proposition of being in a study. Finding the "one word" that resonates (attitudinal research – will reveal these values...but is rarely done), Know who the "keepers" are, and Find the best fishermen. Patient retention requires facilitating equitable exchanges. Attention is linked to patient satisfaction. Aside from the typical method of drop-out/satisfaction tracking, they advocate proactive Retention Planning by assessing these highly relevant factors: Lifestyle impact, Study duration, Medical condition, Clinic visits and relationships.

Overcoming Challenges in Pediatric Clinical Trials: To those unfamiliar with them, clinical trials in children present a different situation than for those in adults. For example, you can't just recalculate results for different body weights! Rick Cutcher, of the ICON DOCS Group, explained these differences during his talk.



Photo by Eva Pastor
Nearly 100 professionals learned about the Tricks, Tips and Tools of the Clinical Research trade.



Photo by Linda Ubelacker
Dale Rosin, MD, BC Coaching Resources



Photo by Linda Ubelacker
Sandy DiGiambattista, Chapter President, presents awards of gratitude to the Conference Planners.



Photo by Linda Ubelacker
Thanks to our sponsors!

Participant Perspective:
"I liked the program. Very well-rounded."
-Mona Jacobs-Small



Photo by Eva Pastor
Nancy Pultorak, University of Pennsylvania

2010 2-Day Educational Conference Recap

Day 2

Perspectives on Central and Local IRB Review: Kyle Conner of Jefferson IRB and Cami Gearhart of Quorum IRB gave us an overview of the factors affecting the choice of a Local or a Central IRB for a clinical trial. They discussed the regulatory environment, how federal regulators are affecting the industry, and what they see in the future for the IRB industry. Finally, they spoke of their experiences with local and with central IRBs and with managing the ethical review system their own IRBs. Finally, they briefed us on the fallout from the GAO's "sting" operation that ensnared Coast IRB and led to their shutdown. They provided recommendations on how to prevent this from happening again such as accreditation, education, and affiliations between central and local IRBs.

Project Management Tips for CRAs: Yvonne Albright, Jill Drummond, and Marjorie Rossomando of Covance gave an insider's view of the preferred skill set for CRAs and SCs (those that give themselves over to the *other* side). Included in that skill set are knowledge of GCP, CRF completion knowledge, clear visit objectives, professional dress, professional demeanor and attitude. Finally, a collaborative relationship between the sponsor and the site is a key to success. We develop this by Respect each other's time, Define best methods of communication, Schedule telephone calls (with predetermined times, agenda, lengths) , Investigator Meetings, PI/IRC teleconferences, and Monitoring visits. If CRAs and CRCs focus on the above, and respect for each other, they will develop closer relationships, and work better together.



Photo by Eva Pastor
Deidre Adore presents a raffle prize to a Conference Participant

Tips on the Condition of Job Burnout: Dr. Dale Rosin, along with Edie Commodaro and Karoline Borup of BC Coaching Resources, presented a topic near and dear to all in the industry today...job burnout. They spoke of the signs, symptoms, and treatments, as well as some advice on how individuals might fight, or even prevent it in ourselves. Whether work-related or lifestyle-related, burnout is a significant organizational and personal issue. But it CAN be managed, and even prevented, if we strive to provide ourselves with a balance of activities. For those stricken, the presenters described the common therapies of psychotherapy and psychopharmacology. They went on to describe a basic set of steps we can all use to prevent burnout: Start the day with a relaxing ritual, Adopt healthy eating, exercising, and sleeping habits, Set boundaries, Take a daily break from technology, Nourish your creative side, Pay attention to yourself, and Recognize the warning symptoms.

Tips for Cardiac Safety in Clinical Trials: Tim Callahan of Biomedical Systems gave us a very informative talk about cardiac biomarkers and their significance for patients, regulators, and sponsors. He discussed the typical cardiac safety biomarkers in many trials and described the methodology of determining these values, and the limitations of both the indicators themselves, as well as the techniques for measuring them. Thus, it is important to be careful when choosing indicators of cardiac safety, and building-in measurement methods into our studies. Both must be valid for them to be worthwhile in providing data.



Photo by Eva Pastor
Tim Callahan, BioMedical Systems



Photo by Linda Ubelacker
Armand Spoto, Lernia

Solutions for Improving Academic Clinical Trials, and Improving Relations with Industry Partners: Nancy Pultorak discussed the University of Pennsylvania's evolving clinical research enterprise. The industry is loading more and more onto the shoulders of research coordinators and site staff, and then

wonders why they can't deliver. They were given the task of mounting an FDA-mandated response to the Jesse Gelsinger incident. Subsequently, their efforts have produced industry-pioneering examples, such as the Penn Manual for Clinical Research, and the Internal Auditing Office that assesses every Penn Investigator annually. To get buy-in, they even sponsor a Principal Investigator Retreat and online PI training program. Their Core Best Operational Practices are a prime example of applying a pragmatic viewpoint to existing industry best practices. Finally, in a step that provides significant cost, time and energy savings to all Penn clinical trials staff, they provided a direct answer to counter the overloading of Research Coordinator responsibilities by contracting to provide the Velos CTMS for all Penn Investigators.



Photo by Linda Ubelacker
Maria Monshaw, CCRA

I leave the hotel newly invigorated. I am energized by what I've heard, and the new and innovative ways people are thinking about clinical trials. I am energized by being a part of this group.



Photo by Eva Pastor
Relieved Conference Planners Deidre Adore and Jill Herring, and Day 2 emcee Jeff Collins

Participant Perspective:

"[The Conference] was really great! Glad I came. When you are isolated, working independently, it's good to hear other points of view."

-Jaime Koh

<http://www.acrpn.net.org/GetInfoFor/USChapters/GreaterPhiladelphia.aspx>



Partnering with Academia for Education

By Lisa Desiderio

The ACRP Greater Philadelphia Chapter has been expanding to include an academia/industry perspective. It started with a collaborative effort between the University of Pennsylvania and ACRP at the first annual recognition event at Penn for Clinical Research Coordinators, an event given for the Society of Clinical Research Coordinators and Project Managers to include a Professional Development and Education Committee that enhances clinical research education both within and outside the institution.

One of the committee's initiatives was to provide a forum for the coordinators to learn more about national organizations like ACRP with a focus on membership and certification. To accomplish this initiative, UPENN hosted a local chapter event for ACRP in November 2007. The development of this partnership continued with other events hosted in 2008 and 2009 by Children's Hospital of Philadelphia and UPENN, respectively. Topics included an academic and industry perspective with some great discussions on recruitment and retention, core best practices in clinical research and the support of clinical research with the addition of the American Recovery and Reinvestment Act also known as the "ARRA" or "Stimulus Funding" from the National Institutes of Health.

This year the meeting will be hosted by Lankenau Hospital with a focus on "Bench to Bedside in Clinical Research". The ACRP Greater Philadelphia Chapter will continue these collaborative relationships and find new approaches to enhance clinical research for the ACRP members as the chapter continues to evolve in the Philadelphia region.

AWARD WINNING CHAPTER



**Greater Philadelphia Chapter of ACRP
2010 Outstanding Chapter Award Winner**

**Thanks to Dan Schmincke for accepting
our award at the ACRP Global Conference
in Tampa, Florida, in April.**

Career Distinction Key at May Dinner Meeting

By Deidre Adore

On Tuesday, May 25, 2010, BIOCLINICA, Inc. in Audubon, PA sponsored the event "Career Distinction – Stand Out by Building Your Personal Brand" presented by Cindy Monroe, Partner/VP of Twin Image Recruiting, LLC.

Ms. Monroe provided a presentation explaining how a Personal Brand Statement (PBS) can be a powerful marketing tool for career distinction and success. The PBS is about honing your skills, narrowing your focus, and getting clear about your passion so you will draw people and opportunities to you like a magnet. A short PBS (composed of 2-3 sentences) will enable you to market yourself quickly whenever a chance of networking arises. Both employers and colleagues will recall/identify you by your memorable "**catchphrase.**"

After the presentation, attendees broke into groups to participate in hands-on experience activities as well as brain storming sessions with industry peers to develop a concise niche PBS. Ms. Monroe provided the following tips for creating successful personal branding statements:

- Identify your unique attributes
- Be honest about your passion and goals so your "reflective" statement holds up
- Gain Recognition - Target an Industry/Audience where your skills are most beneficial
- Create a concise compelling statement
- Nurture and grow yourself by taking the time to revise your PBS once a year

As a result of this workshop, members left the meeting eager to align the compelling statements by updating our resumes, business cards, websites, personal blogs, Social Network/Accounts (e.g., LinkedIn, MySpace, Twitter, and Facebook ,etc.) to promote a strong and consistent career overview.

A special thanks to Peter Benton, President, eClinical Division, BIOCLINICA, and his staff for their gracious hospitality in hosting the event, as well as to Cindy Monroe for her exceptional workshop.



Photo by Linda Ubelacker

Cindy Monroe works with a small group of attendees to develop a PBS.