Don't Miss The ***NEWEST*** Conference From The Advanced Learning Institute's Acclaimed Training Series, Specialized For Pharma Sponsors, CROs, Biotech And Healthcare

Patient Recruitment, Compliance And Retention For CLINICAL TRIALS

Integrating The Latest Technologies With Traditional Tools To Maximize Patient Engagement

Register by Aug. 31st To Save $400!

October 25 - 26, 2011 - New York, NY

WHAT YOU WILL LEARN

Attend this conference to learn how to integrate the latest clinical trial recruitment and compliance technologies with your traditional methods for maximum patient engagement, by:

- **Reducing** recruitment time with online screening and Electronic Health Records (EHR)
- **Monitoring** patient behaviors with social media and mobile devices
- **Working** more effectively with patients and family members to increase compliance and build relationships
- **Continuing** conversations with patients after the trial is complete
- **Using** new technologies to meet deadlines and keep patients engaged
- **Integrating** new media tools to improve the effectiveness of your study
- **Increasing** accuracy by implementing ePRO (electronic patient reported outcomes)
- **Identifying** the right trial participants by reviewing EHR
- **Facilitating** compliance by connecting with patients where they're most comfortable
- **Finding** qualified patients by accessing online communities, networks, and advocacy groups
- **Overcoming** the patient recruitment bottleneck through outsourcing
- **Building** an organizational culture that supports new patient engagement technologies
- **Targeting** various demographics with online advertising
- **Creating** patient-driven online communities as a means for validating interest in clinical trials participation
- **Understanding** how interactivity with patients encourages participation
- **Obtaining** patient compliance by using mobile technologies to engage participants
- **Understanding** the confidentiality issues with trial sites and online communities
- **Eliminating** the need for routine hospital visits by running a strictly "virtual" clinical study

SUPPORTING ORGANIZATIONS

pharmaphorum bringing healthcare together · BioCrowd · BioJobBlog

SPEAKING ORGANIZATIONS:

Hear practical, real-world solutions and learn best practices on how to achieve successful patient recruitment, compliance and retention in your clinical trials from practitioners at these top organizations:

Pfizer
Merck Research Laboratories
INC Research
Quintiles
Shire Pharmaceuticals Ltd.
United BioSource Corporation
Quorum Review IRB
Montefiore Medical Center
Celgene Corporation
MediGuard.org
Staley Media Services
Hamilton Medical Consultants Group
Omniscience Mobile
PRA International
Theorem Clinical Research
Allos Therapeutics
The Michael J. Fox Foundation for Parkinson's Research
SiteAvail, Inc.
HealthCentral.com
Greenphire LLC
Albert Einstein College of Medicine

Presented by:

Advanced Learning Institute

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Register by August 31st to Save $400! • Bring a Team and Save – Register 3, Send a 4th for FREE!
To Register, Call (888) 362-7400 or (773) 695-9400 or online at www.aliconferences.com

WHO WILL ATTEND:

This conference has been researched with and designed for Directors, Managers, Senior Vice Presidents, Vice Presidents, Coordinators, Officers, Leaders and Consultants involved in:

Clinical Operations

Patient Recruitment

Clinical Services

Trial Optimization

Clinical Data Management

Online Patient Communities

ePRO (electronic patient reported outcomes)

Clinical Development

Patient Engagement and Compliance

Clinical Studies

Study Monitoring

Clinical Research

Clinical Trials

Including pharma sponsors, CROs, IRBS, and all those interested in learning how to integrate the latest technologies with traditional tools to maximize patient engagement in clinical trials.

WHY IS THIS A CAN'T MISS EVENT?

Current recruitment methods simply aren't bringing enough patients into clinical studies. New processes and technologies integrated with traditional methods are imperative to reaching new patient populations and ensuring engagement. Several organizations are making dramatic strides in developing approaches and systems that work for them. The periodic sharing of these experiences and "best practices" is an important element in this clinical trial evolution. That is why this forum, presented by the Advanced Learning Institute, is such a valuable opportunity to hear perspectives and share experiences of other clinical trials professionals engaged in the "journey."

THE COMPETITIVE ADVANTAGE YOU'LL GAIN FROM ATTENDING THIS CRITICAL EVENT

This conference is a must-attend event for all those who are committed to finding new ways to recruit, retain and engage their clinical trial subjects. You will benefit from:

- **20 innovative speakers** at your disposal to share their strategies and experiences in using new technologies and traditional strategy for recruitment, compliance and retention
- **Over 15 hours of intense, interactive learning** - we guarantee you will recoup your money spent by implementing just a few of the strategies shared during the conference
- **Networking lunches** that give you the opportunity to brainstorm and benchmark solutions with your fellow attendees
- **An abundance of networking opportunities** -- be sure to bring plenty of business cards as you will make many new contacts
- **A comprehensive overview** of clinical trial strategies from leading pharma sponsors, CROs, and other industry practitioners like **Pfizer, Kendle International, PRA International, Merck Research Laboratories**, and many more
- **Acquiring new knowledge** to help transform your strategies and impact your organization's bottom line
- **Participating in instructional sessions** that will share real-world examples, tactics and lessons learned in maximizing patient engagement that will ground you in advancing your own strategy
- **A complimentary packet of research materials** that will serve as a helpful resource long after you have attended this conference
- **A formal Certificate of Completion** which documents your training achievement and commitment to continuing professional development

Collaborate Using the Conference Wiki:

All attendees will be invited to expand their networks and continue their conversations via the conference wiki --- an online tool providing speaker materials, additional resources and an opportunity for you to keep in touch and collaborate with your colleagues after the event.

A LETTER FROM THE CONFERENCE CHAIRPERSON

"The greatest mistake in the treatment of diseases is that there are physicians for the body and physicians for the soul, although the two cannot be separated."

Plato, - 400 BC

Dear Clinical Trials Professionals,

Treat the person, not the disease. Plato understood that. After all, clinical trial participants are more than the sum of their medical troubles – each has their own hopes and fears which we should strive to understand to make the clinical trial process more agreeable to all involved (sites and CROs, included). But we already do this, don't we? Well, according to the statistics, no. Recent data have shown 75 percent of investigators fail to enroll the target number of patients and the average dropout rate for clinical trials stands at 30 percent.

So, why the poor numbers? A key factor is the general population's misperception of clinical trials. People simply lack a basic understanding of the clinical development process which in turn breeds apprehension – and an uncertain patient is not likely to enroll or follow through with a study.

For an added degree of difficulty, modern clinical trials are becoming more and more complex and require larger numbers of highly-specific patient populations. Competition for patients is fierce. ClinicalTrials.gov alone currently shows more than 29,000 open trials requiring millions of patients globally. To recruit, and just as importantly to keep these patients, we are going to have to do a better job of education and engagement.

There are many wonderful ongoing initiatives aimed at improving perception, but we can do more. We need to educate people about clinical trials before they begin, support them during a study and provide them with guidance once a trial ends. During this conference, leading patient recruitment and retention experts will share their strategies on addressing such challenges, including how:

- **Pfizer** is launching the first ever randomized virtual clinical trial where patients can participate entirely from home – no matter how far from the investigator site
- **Partnership to Accelerate Clinical Electronic Research (PACeR)** is creating an economically sustainable, electronic clinical research data network to more efficiently identify potential candidates for clinical research trials and manage their care
- **Allos Therapeutics** engages patients with rare diseases by developing relationships with advocacy groups, cooperative organizations, and Key Opinion Leaders (KOLs)

You'll also hear how online screening and Electronic Health Records (EHR) can reduce recruitment time, working with families (not just patients) helps minimize discontinuations and utilizing the right technologies helps to support your patient recruitment strategy.

One topic we're particularly excited to be covering is the use of social media. Social media is changing the way we communicate and, according to a recent study, the effective utilization of the tool can accelerate research by increasing the number of participants and reducing study costs.

Don't miss your chance to learn all of this and more! Register today online or call our conference hotline at 888-362-7400 to attend the Advanced Learning Institute's conference on "Patient Recruitment, Compliance and Retention for Clinical Trials," this October in New York. **This is your opportunity to hear from leading clinical trials professionals and organizations that are already using the latest strategies to maximize patient recruitment and engagement.**

I look forward to welcoming you to this information-packed event.

Kind regards,

Jeffrey Zucker, Senior Director & Global Head, Feasibility & Patient Recruitment
INC RESEARCH
Conference Chairperson

P.S. Reserve your spot today to learn how you and your clinical trials team can improve your recruitment, compliance and retention efforts. Register 3 people and get the 4th for FREE! Click here for details or call (888) 362-7400.

General Sessions - Day One - October 25, 2011

8:00 a.m.
Registration & Continental Breakfast

8:30 a.m. CHAIRPERSON'S ADDRESS
Chairperson's Welcome & Presentation:
Building A Successful Recruitment Campaign Using A Balance Between Investigator Site Engagement And Patient Outreach

Gaining a full understanding of the impact patient recruitment efforts have on clinical trials has been an ongoing process involving more and more research professionals in both industry and academia. Those who have been working in the field for some time have witnessed an evolution that continues to gain momentum. The focus of efforts in the patient recruitment field has shifted and diversified rather significantly over the last decades from being driven by primary communication with the investigators to more creative and direct ways to reach out to potential subjects.

Blending investigator and patient engagement and motivation can be the key to a successful recruitment campaign for many clinical trials. Of course, no one plan, strategy, or tactic is applicable to every clinical trial, but there are fundamental aspects that nearly every study should be based upon - - a recruitment plan, whether enrolling 10 or 10,000 patients, with milestones to measure success and full contingencies to employ when enrollment is off track.

Come explore the world of effective patient recruitment as you discuss how to combine strategies and tactics that involve both investigative site engagement and patient outreach.

You'll learn the importance of:

- Achieving a balance between these key areas as driven by the patient population, countries being utilized, and many other factors
- Treating each trial individually - no two are alike
- Building a highly-tailored and specific plan that considers the use of the ever-growing amount of tools available in the industry through engagement, communication, and motivation of both your sites and patients

Jeffrey Zucker, Senior Director & Global Head, Feasibility & Patient Recruitment
INC RESEARCH

9:30 a.m.
Break-Out Blitz!
Network And Discuss Your Challenges With Your Fellow Conference Attendees

This session will open the conversation by connecting you with other conference participants and gain greater understanding into many similar issues, concerns, and challenges that your peers are also facing. Become acquainted with your fellow conference attendees in this fun and fast-paced forum!

9:50 a.m.
Morning Refreshment & Networking Break

10:15 a.m. SPECIAL PRESENTATION
How To Improve Patient Participation And Access Using Virtual Clinical Trials

Clinical trials are long and complex research studies that rely on the self-sacrifice of patient participation and data sharing. In recent years, a number of interesting trends in healthcare have emerged: patients are much more engaged in participatory medicine; they're willing to share their health data to benefit public health and research; and they turn to the Internet for health information.

In June 2011, Pfizer announced plans for leveraging these patient trends to conduct the first-ever randomized clinical trial under an investigational new drug (IND) application where patients can participate entirely from home – no matter how far from the investigator site. As a Participatory Patient-Centered (PPC) clinical trial pilot, Pfizer expects the new model to provide new opportunities for patients to access clinical studies. As partners in the research, patients will have access to

all study results and their own clinical data. Patients can then use this data to manage their own health and wellness, and even share the data with their doctors.

The pilot to test this new approach is "REMOTE" - - Research on Electronic Monitoring of Overactive Bladder (OAB) Treatment Experience - - the results of which will be compared to a previous brick and mortar trial for OAB treatment. By examining this innovative project, you will walk away with a number of ideas on how to:

- Use multimedia/video and online testing to secure patient consent
- Manage your patients in an entirely remote manner including shipping all blinded study medication to patients at their homes
- Save time and obtain better quality, more reliable data
- Increase patient compliance and lower withdrawal rates

Craig Lipset, Head of Clinical Innovation
PFIZER

11:00 a.m. CASE STUDY

Best Practices In Patient Recruitment Outsourcing – Why The Patient Should Be At The Center Of Your Strategy

Patient recruitment firms continue to evolve and learn, gaining new decision support data and metrics along the way. However, pharma sponsors have not kept pace with regard to providing more sophisticated input to the outsourcing process.

This presentation will peel back the curtain on the prevailing conventions for patient recruitment outsourcing and offer you novel alternatives to improve your engagement efficiency. You'll leave this session prepared to create a more collaborative environment where finally, the patient is placed at the center of the strategy.

In particular, you will learn:

- Dynamics of local adoption for recruitment tactics
- Alternatives for supporting strategy development
- The patient-centric model and how to apply it to your organization's efforts

Joseph Kim, Director of Clinical Operations
SHIRE PHARMACEUTICALS LTD.

11:45 a.m.

Lunch On Your Own -- But Not Alone!

Join a group of your colleagues for lunch with an informal discussion facilitated by one of our expert speakers. Take this opportunity to connect with others in a small, interactive group setting to network and brainstorm solutions to your most pressing recruitment and retention concerns.

1:15 p.m. CASE STUDY

Building An Organizational Culture That Supports New Patient Engagement Technologies

Patient engagement technologies have been available for many years, but adoption of these innovative tools is still not widespread among clinical trials for many reasons. One key area that will assist with increasing adoption levels is to build an organizational culture that supports new patient engagement technologies. At its core, this is a change management exercise. Since change never happens easily, a methodology must be followed in order to achieve the desired result.

Specifically, a clear vision must be set, the organization has to be aligned with that vision and all employees/members of the organization must be motivated to prepare for and adapt to the changes needed.

Reviewing change management strategies and tools as experienced at both Wyeth and Theorem Clinical Research, this session will examine how your organization – whether big pharma or CRO – can approach new technology implementations for successful results, including:

- Establishing a sense of urgency and creating a powerful guiding coalition
- Communicating the vision through all possible vehicles
- Developing a knowledgeable implementation team
- Empowering others to act and making the changes stick

Michael Burton, Senior Director, Site Management and Patient Recruitment
THEOREM CLINICAL RESEARCH

2:00 p.m. CASE STUDY

How To Harness Social Media And The Internet To Recruit Potential ePatients: A Step-By-Step Process

Recent reports have shown that the Internet is currently the most popular resource for seeking health information -- even more so than consulting with medical professionals. It's clear that the Internet is changing the way people think about their medical care. Consequently, pharma organizations can benefit from this strategic change by accessing a new, motivated pool of patients for clinical trials. This strategy can reduce patient advertising costs while reaching a larger and more focused audience quicker than more traditional recruitment methods. However, the lack of regulatory guidance in this area has impeded many companies from this approach.

Like other patient recruitment strategies, Internet-based advertising must be properly planned to effectively enhance patient recruitment and target motivated patients.

During this session, you'll walk through LEO Pharma's journey of introducing social media into their recruitment strategies. Examining each step – from vendor selection through program implementation – you'll gain a greater understanding of the impact and potential roadblocks that can occur. You'll also acquire tips for success in your own electronic recruitment program, including how to:

- Identify which social media method would be most appropriate for your clinical trial
- Tap into patient advocacy blogs as well as physician and disease-specific websites
- Utilize search engine marketing – including geo-locating ad placement
- Implement tools to measure your results (i.e. Google Analytics)
- Recruit within the current regulatory guidance on using social media tools

Rodney Butt, Principal
HAMILTON MEDICAL CONSULTANTS GROUP
Former Head, Clinical Operations
LEO PHARMA INC.

2:45 p.m.
Afternoon Refreshment & Networking Break

3:00 p.m. CASE STUDY

How To Increase The Accuracy Of Your Clinical Trials By Implementing Electronic Patient Reported Outcomes (ePRO) And Clinician Reported Outcomes (ClinRO)

The FDA issued guidance on the use of ePRO in Dec 2009. The decision to incorporate ePRO in clinical trials is

multifaceted and must be considered carefully by the study team. Consensus by the team must be achieved prior to embarking on the use of ePro. Additionally, Clinician Reported Outcomes (ClinRO) is a hotly-debated industry topic and should be considered early in the design process and may influence how the data will be presented.

This session will provide you with guidance on the following topics:

- Key criteria for choosing to use ePRO in a trial and the considerations that must be made
- Pointers on discussion and decisions that should be made
- Criteria for adopting ClinRO in clinical trials and the advantages and disadvantages
- The potential impacts of using ePRO and ClinRO (budget, time, manpower, etc.)

Elisabeth Kurkimilis, Sr. Operations Manager
CELGENE CORPORATION

3:45 p.m. CASE STUDY

Identifying And Engaging Rare Disease Patients Via Alternative Avenues: How To Develop Relationships And Work With Cooperative Groups, Advocacy Groups, And Key Opinion Leaders

The development of new drugs requires sponsors to evaluate the safety and efficacy of their compound in a given patient population. In most instances, sponsors are able to rely on data and existing published medical literature that effectively describe symptoms, management and outcome measures unilaterally or in comparison with other disease modalities or treatment options.

Orphan indications, or rare diseases, do not have the luxury of robust “best practices” and historical data that make the development and regulatory pathways less complex or clear. The National Institutes of Health defines an orphan or rare disease to be one that affects less than 200,000 patients per year in the United States. Consequently, developers of orphan drugs have to better understand their target indication, work closely with key opinion leaders (KOLs) and clinicians, work harder to reach their patients and educate regulators on disease state and the impact of their drug on patient outcomes.

This session will discuss alternative avenues for identifying and engaging patients with orphan disease states to participate in clinical trials. Regulatory and legal considerations will be discussed as well. You’ll gain a broader understanding of the challenges to patient recruitment in specialized disease states and learn effective solutions to overcoming those challenges, including:

- Leveraging alternative avenues to increase trial enrollment
- Understanding what these options are and what they aren’t
- Staying within the boundaries of legal and compliance regulations
- Managing relationships with KOLs

Lynn Sutton, RN, NP, Vice President Clinical Services
ALLOS THERAPEUTICS

4:30 p.m. CASE STUDY

Academic Medical Centers And Clinical Trials - Can They Peacefully Coexist?

Over the past decade, clinical trial work has migrated out of the traditional academic medical center into community-based practices as well as overseas. Part of the driver of this change in site location has been the recognition that academic centers have been less efficient in getting trials activated, and academic physicians often less successful in recruiting and retaining subjects. The migration of clinical trials away from academic centers has served to marginalize key opinion leaders and their participation in trial work.

The Albert Einstein College of Medicine and Montefiore Medical Center have made a concerted investment in re-engineering their infrastructure to support and attract trials to their center, physicians and patients. In the past year, they have assembled an office to offer support, guidance and help to principal investigators and their study coordinators.

In this informative session, through the experiences of The Albert Einstein College of Medicine and Montefiore

Medical Center, you will hear about the efforts to increase the efficiency and effectiveness of clinical trial activation, management, and implementation, as you learn of the:

- Nature of the problem
- Re-design of processes and systems to support and streamline trials
- Approval and activation within an academic medical center
- Build out and design of an Office of Clinical Trials designed to facilitate and not obstruct successful trial completion

Barrett Katz, M.D., M.B.A., Executive Director, Office of Clinical Trials
MONTEFIORE MEDICAL CENTER

Frances DeJur Chair in Ophthalmology -&- Professor of Ophthalmology, Neurology & Neurosurgery
ALBERT EINSTEIN COLLEGE OF MEDICINE

5:15 p.m.
End Of Day One

5:20 p.m. 
Networking Reception: Please Join Us!
We invite you to join us for a drink as you relax with your peers. All conference attendees and speakers are welcome to join us for this special opportunity to continue networking. Don't miss this chance to benchmark new ideas over complimentary drinks!

7:00 p.m. 
Dine Around
Sign up during the day for dinner with a group. Take advantage of New York City's fine dining while you continue to network with your colleagues.

General Sessions - Day Two - October 26, 2011

8:00 a.m.
Continental Breakfast & Networking

8:30 a.m.
Chairperson's Opening Of Day Two
Jeffrey Zucker, Senior Director & Global Head, Feasibility & Patient Recruitment
INC RESEARCH

8:45 a.m. CASE STUDY
How To Leverage The Role Of Your Clinical Research Associates (CRAs) To Support Successful Subject Recruitment And Study Conduct

Many companies are choosing to spend more time and resources on clinical trial monitoring and relationship building. To achieve success, a company must work to change the perception of the sponsor-site relationship. As a result, CRAs should begin to treat their sites more like customers so they can build better working relationships.

Benchmark best practices with a former Patient Recruitment Specialist from sanofi-aventis, as you learn how to empower your CRAs to liaise with study sites more effectively for maximum productivity. While reviewing examples of opportunities where CRAs can be more involved in all aspects of the clinical trial process, you will learn:

- Practical ideas to improve site relationships – including tips for defining goals and expectations when discussing enrollment plans
- Benefits of better site communication
- Steps to ensure the ROI of territory development activities

Gretchen Goller, Director of Patient Recruitment
PRA INTERNATIONAL

Former Patient Recruitment/Compliance Strategist – Operations
SANOFI-AVENTIS US, INC.

9:30 a.m. CASE STUDY
Using Mobile Technology To Improve Patient Recruitment Results

There is a well known need for clinical research technologies to 'catch up with their patients.' Mobile phones are a classic example of this issue, where the vast majority of trial participants have mobile phones and are using them to send/receive text messages. This offers an exciting opportunity for studies to use mobile phones (and text messaging, in particular) to accelerate recruitment and enrollment timeframes.

United BioSource Corporation and Omniscience Mobile have partnered together on multiple clinical studies for various pharma sponsors in recent years. Sharing these experiences, this session will demonstrate how text messaging can be incorporated in traditional patient recruitment advertising to drive improved results. With a pragmatic eye for the key implementation considerations, this session will help you understand:

- Relevant market data on the use of mobile phones and text messaging
- Exactly how text messaging is incorporated in patient recruitment advertising
- Tracking ROI on text messaging as a response mechanism
- Using text messaging to track media spend ROI
- Detailed results from previous clinical studies
- Lessons learned during early implementations
- The type of studies and patient populations that are well-suited for incorporating this technology

Patient recruitment is one of the easiest (and most important) areas to use technologies preferred by study patients. Come learn how you can add this tool to your recruitment efforts and start achieving results immediately!

Tess Drahzal, Director: Patient and Physician Services
UNITED BIOSOURCE CORPORATION

Jeff Lee, CEO
OMNISCIENCE MOBILE

10:15 a.m.

Morning Refreshment & Networking Break

10:45 a.m. CASE STUDY

How To Make Clinical Trials More Patient-Friendly: Insights From The World's Largest Online Patient Community

Historically, knowledge of what motivates patient interest in research has been limited to reports from physician investigators or anecdotal feedback from CROs and other patient recruitment organizations. With the rapid growth in individuals seeking health-related information online and the emergence of social media, opportunities to engage patients about the design of and participation in clinical trials has increased significantly.

MediGuard.org—a free medication monitoring service with over 2.5 million consented members in the US, UK, France, Germany, Spain, and Australia—regularly engages in direct-to-patient research activities including clinical trial feasibility, clinical trial recruitment, observational research studies, and compliance/adherence programs.

This enlightening session will share key findings from survey results from over 2500 patients across 32 different patient protocol feasibility assessments. You'll gain important insights into how you can design studies that are more acceptable to patients, including the:

- Variances in the levels of patient engagement and receptiveness to research based on their specific condition
- Factors correlated to patient interest in study participation and the significant drivers
- Importance of subject compensation in study interest
- Actions that can improve enrollment and patient retention

If you're interested in hearing more about what your patients are saying and how to make your clinical studies more patient-friendly, then you won't want to miss this session!

Elisa Cascade, MBA, Vice President, Global Operations
MEDIGUARD.ORG

11:30 a.m. CASE STUDY

Using Social Media To Engage Patient Opinion Leaders To Advance Your Clinical Trials And Research

Patient communities rank among the most active and engaged groups in the social networking space. Pharmaceutical companies and research teams can build more dynamic platforms by reaching out to key patient communities to help promote and review their current research objectives.

When looking to recruit new patients for clinical trials, these communities are often overlooked – but they should not be forgotten. Hear from an involved patient activist how your organization can create a strategic plan that will help you reach out to the appropriate patient community for your clinical trial.

You won't want to miss this insightful presentation that will:

- Discuss the ground rules for pharma sponsors and CROs interested in engaging Health Activists and patients online
- Explore the means for keeping patients active and engaged throughout the life cycle of your clinical research and into the product launch

- Provide examples of those who are effectively collaborating with their patient communities

Alicia Staley, Cancer Health Activist and Patient Expert
STALEY MEDIA SERVICES

Ann Bartlett, Diabetes Patient Expert
HEALTHCENTRAL.COM

12:15 p.m.

Lunch On Your Own -- But Not Alone!

Join a group of your colleagues for lunch with an informal discussion facilitated by one of our expert speakers. Take this opportunity to connect with others in a small, interactive group setting to network and brainstorm solutions to your most pressing recruitment and retention concerns.

1:45 p.m. **PANEL DISCUSSIONS**

Innovative Technologies For Patient Recruitment And Engagement: A Panel Discussion On What You Need To Know

Patient recruitment is just one area that has seen advances due to new technology developments. Social media, mobile devices, and open source software solutions are increasing engagement and compliance levels that are imperative for clinical researchers to see a successful trial through to the finish.

A variety of new innovations will be showcased and debated in this lively forum. Take this opportunity to compare and contrast different technologies, firsthand, and get your most pressing questions answered in this lively, interactive forum.

Laura Dalle Pazze, Associate Director, Research Partnerships
THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

Daniel Weddle, President & Founder
SITEAVAIL, INC.

Samuel Whitaker, Co-founder & CEO
GREENPHIRE LLC

2:30 p.m.

Afternoon Refreshment & Networking Break

2:45 p.m. **CASE STUDY**

Third Parties And Clinical Trials: Who They Are And How To Involve Them For A Successful Trial

Human Subject is defined in the Common Rule as a "living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information." The FDA defines a Human Subject as “an individual who is or becomes a participant in research, either as

a recipient of the test article or as a control." In certain types of research, it can be difficult to determine whether a third party (aka secondary subject) involved in a study – i.e. pregnant partners, newborns, caregivers, or family members – meets these definitions and therefore should be classified as a research subject as well.

It is important for both researchers and Institutional Review Boards (IRBs) to consider how a research design might focus on these individuals and the appropriate protections that may be needed, such as: incorporating third parties in the research design of the protocol, obtaining informed consent/authorization, data security and confidentiality protections, and considering the dissemination of hereditary genetic results. By understanding the role that third parties play in research, you will leave this session prepared to:

- Identify when partners, caregivers, and other third parties are research subjects under HHS and FDA regulations and guidelines
- Understand informed consent and HIPAA considerations for third parties
- Implement appropriate protocol language considerations from the perspective of an IRB

Deborah Holland, JD, MPH, CIP, Regulatory Attorney
QUORUM REVIEW IRB

3:30 p.m. **CASE STUDY**

The Partnership To Accelerate Clinical Electronic Research (PACeR): A Collaborative Solution For Improving Clinical Trial Modeling, Patient Selection, Trial Management & Safety Surveillance

The goal of the Partnership for Advancing Clinical electronic Research (PACeR) is to increase the speed, quality, and efficacy of clinical studies, helping to provide patients with quicker access to new, treatments and life-saving medicines. PACeR is achieving this goal by designing and launching an economically sustainable, electronic clinical research data network across New York State to more efficiently identify potential candidates for clinical research trials and manage their care.

PACeR stands apart from other attempts to improve the clinical research process because of its inclusiveness and responsiveness to the needs of multiple stakeholders. The Healthcare Association of New York State (HANYS) serves as a neutral partner and coordinator, bringing together multiple medical centers, health systems, community hospitals, patient representatives, pharmaceutical companies, health information technology companies, and others to engage in a multi-year collaborative. The guiding principle behind this endeavor is the benefit to patients. Ensuring robust patient privacy and consent protections is paramount.

In this fascinating session, you'll learn how this forward-thinking collaborative can serve as a viable, practical model for other states, regions, and the nation, by developing solutions to relevant technical, legal, regulatory, economic, and operational issues of clinical studies.

Gary Mallow, Director, Health Information Technology for Clinical Research
MERCK RESEARCH LABORATORIES

John Murphy, Head of Clinical Analysis
QUINTILES

4:15 p.m.

Chairperson's Recap: Key Takeaways And What To Do When You Get Back To The Office

We'll recap the highlights of the past two days and ask you to share key insights and next steps with the group.

4:30 p.m.

Close Of General Sessions

CONFERENCE SUPPORTERS:

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For more information, please go to: http://www.biojobblog.com.

RAVE REVIEW FROM A PAST CONFERENCE ATTENDEE:

"I loved the size and focus of this conference. Best peer conversation I've ever had at an event..."
L. Lopez, Associate Director, Web Communications
GENZYME

ALL CONFERENCE SESSIONS WILL BE HELD AT THE:

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The following are included in your conference registration: attendance, a detailed conference workbook and any additional meeting materials - - including access to the conference wiki, continental breakfasts, morning & afternoon refreshments, and evening networking reception.

Group Discount: Register 3 colleagues and the 4th is FREE!	**Earlybird Pricing: Register with payment by August 31st**	**Regular Pricing: Register with payment after August 31st**
Conference: October 25 & 26, 2011	$1,499	$1,899
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*IL residents will be charged 9.25% sales tax on workbook orders.		

Payment is due two weeks prior to the conference. If payment has not been received two weeks before the conference, a credit-card hold, training form or purchase order will be taken to ensure your space.

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A.L.I. reserves the right to make changes in programs and speakers, or to cancel programs if enrollment criteria are not met or when conditions beyond its control prevail. Every effort will be made to contact each enrollee if a program is canceled. If a program is not held for any reason, A.L.I.'s liability is limited to the refund of the program fee only.

CANCELLATION POLICY:

You may make substitutions at any time; please notify us as soon as possible. If you cancel (in writing) more than two weeks prior to the conference (before October 10th) a refund will be provided less a $295 administration fee. Registered participants who do not attend or who cancel two weeks prior to the conference or less (on or after October 10th) will be issued a credit memo. Credit memos will be valid for one year from date of issuance and can be used by anyone in your organization.

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