Patient Engagement For CLINICAL TRIALS

Best Practices For Recruitment & Retention Using Patient-Centric Initiatives

December 9 - 11, 2013 - New York, NY

REGISTER BY NOVEMBER 8TH TO SAVE $400!

WHAT YOU WILL LEARN

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

- **Using** innovative strategies to drive clinical trial performance
- **Identifying** cost-effective and efficient media strategies for patient recruitment
- **Leveraging** the explosion of smartphone and tablet ownership and what it means for clinical research
- **Collaborating** with advocacy groups to improve patient awareness and engagement in clinical trials
- **Mobilizing** the recruitment funnel for improved results
- **Using** an evidence-based behavioral model to develop a patient-centric communications plan
- **Quantifying** patient engagement ROI
- **Building** a bridge between central recruitment and your sites for optimal patient engagement
- **Maximizing** the use of innovative study designs to engage patients directly for research
- **Identifying**, enrolling and retaining patients with chronic conditions
- **Addressing** diversity in designing clinical trials to improve outcomes
- **Identifying** the most effective social media initiatives to enhance enrollment while staying within the current regulatory guidance

CONFERENCE PARTNERS

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PharmaVOICE

Medical News TODAY

WHY IS THIS A CAN'T MISS EVENT?

- ✔ 2 LIVE patient panels
- ✔ Choice of participating in 3 hands-on interactive workshops focussing on key issues that matter to you, and maximize your training experience and time out of the office
- ✔ Networking opportunities throughout the conference to connect with your peers across a variety of organizations including our speakers

SPEAKING ORGANIZATIONS:

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

Merck
PPD, Inc.
Celgene
Acurian, Inc.
Bristol-Myers Squibb
Rebar Interactive
Omniscience Mobile
remedy health media
University of California San Francisco
Accelovance, Inc.
Lionbridge Life Sciences
Medidata Solutions
nutrasource
International Cancer Advocacy Network (ICAN)
Kremidas Consulting
WEGO Health
Hudson Global
BioMarin Pharmaceutical, Inc.
ePharmaSolutions
Quintiles
Montefiore Medical Center
Albert Einstein College of Medicine
PAREXEL
HealthCentral.com

Presented By:

advancedLEARNING INSTITUTE
connect, collaborate, and learn

Register by November 8th 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, Vice Presidents, Specialists, 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

Digital Patients

Patient Retention

Patient Advocacy

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

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 engage, recruit and retain their clinical trial subjects. You will benefit from:

- **18+ innovative speakers** at your disposal to share their strategies, and experiences in using new technologies and traditional strategy for recruitment, compliance and retention
- **2 days 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 **Bristol-Myers Squibb, Celgene, PPD**, and many more
- **Acquiring new knowledge** to help drive cost effective and efficient clinical trials 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
- **Access to the conference wiki** – you'll have the opportunity to collaborate and keep in touch with your colleagues after the event using this social media communication tool

Why Our Conferences Are Different:
We offer TRUE COLLABORATION

We build in dedicated time for attendees to benchmark with each other and share personal experiences. You will leave refreshed, with lots of new industry contacts, and new innovative ideas for your own clinical trial engagement, recruitment and retention initiatives.

A LETTER FROM THE CONFERENCE CHAIRPERSON

Dear Colleagues,

Every day is an opportunity to engage potential study volunteers in a dialogue about clinical research and participation opportunities. Whether it is from direct outreach, healthcare professionals, caregivers, or advocacy groups, the potential exists for improving clinical trial recruitment and retention rates.

Advanced Learning Institute developed this conference to address ongoing and evolving engagement challenges and to promote interaction with subject matter experts. It is an ideal forum for learning, sharing and discussion.

Patient recruitment is not static – it is continually evolving. The challenge is cutting through the "clutter" to reach and engage our target audiences about clinical research. There is a continual need to refine recruitment messaging and develop new strategies and tactics.

In addition to the inherent challenges of competing studies and increasingly more complex protocols, study sponsors, CROs, and solution providers must also address newer challenges, including:

- Emerging markets with diverse cultures
- Technology – leveraging assets and resources
- Segmented populations

You will hear success stories from leading organizations such as:

- **ICAN (International Cancer Advocate Network)** and how integrating patient advocates into the research continuum expedites clinical trials and brings the cost curve down
- **Bristol-Myers Squibb** and how they are addressing diversity in designing clinical trials to improve outcomes
- **PAREXEL & Omniscience Mobile** and how they have collaborated to bring modern technologies to the recruitment field to improve the response levels to traditional patient recruitment advertising

I encourage individuals and teams who are actively involved in patient engagement and outreach to join us as we consider and discuss real-world issues that impact patient recruitment. The presenters are a balanced cross-section of industry professionals with specialized expertise and insight.

Please join us in this exciting opportunity to be surrounded by clinical trial colleagues and subject matter experts. Participate in the discussions, delve into the strategies and depart the conference refreshed with ideas and information for your next recruitment program.

I look forward to meeting you!

David Heck, Business Development Director, Life Sciences
LIONBRIDGE LIFE SCIENCES
Conference Chairperson

P.S. Make your investment pay off even more by bringing your entire team!
Register 3 people and get the 4th for FREE! Call (773) 695-9400 for more information.

INTERACTIVE, HANDS-ON WORKSHOPS

Monday December 9, 2013

Jump-start your conference experience by attending these interactive and practical workshops. These information-packed sessions are a great opportunity to network with fellow attendees while taking a hands-on, common-sense approach to mastering patient engagement that will enhance your understanding of the informative, case study presentations throughout the entire conference.

****** Choose ALL FOUR for Maximum Value and Learning ******

8:00 a.m. to 10:30 a.m. – PRE-CONFERENCE MORNING WORKSHOP A

Registration and continental breakfast will begin at 8:00 a.m. for the morning workshop attendees.

How to Engage And Recruit Patients Using The Internet And Digital Marketing: Practical Steps To Improve Outcomes

Increasingly, the Internet is a key source of health information for patients. According to Pew Internet, 72% of adult Internet users reported that they looked online for health information in the last year.

This trend is what has given rise to the term "epatient." Strictly speaking, epatients are patients who use the Internet and digital tools to access and interact with health information. But the term epatient is about much more than tools. It is about a movement, which is creating a fundamental shift in the way medicine is practiced.

As epatients get increasing access to health information through digital tools, they are becoming newly empowered, engaged, and educated. Though physicians and providers remain an important source of health information, they are no longer the only source. And patients are no longer passive participants in their care. In many cases, they direct it.

Some healthcare professionals view this shift in the balance of power as a threat. Savvy clinical researchers view it as an opportunity. Through the Internet and digital media, we now have virtually unfettered access to potential clinical trial participants. In this session, we'll explore how to open up this access.

You'll leave this workshop with a clear understanding of:

- Developing a strong digital patient recruitment strategy by matching the appropriate digital components to your needs
- Honing your targeting and message by using digital tools for efficient market research
- Meeting patients where they are by increasing your online visibility among the right patients at the right time
- Engaging patients with your message and converting them into clinical trial participants by optimizing your digital presence

We will address hot topics in patient engagement (social media). But we'll also discuss some often-neglected topics that can have profound results for patient recruitment. The latest is not always greatest for your particular needs. For this reason, our focus is on practical steps to improve outcomes, rather than any one particular tool. Be prepared to take home strategies and tactics that you can begin implementing immediately.

WORKSHOP LEADER: Rahlyn Gossen, Principal, Rebar Interactive. Rahlyn Gossen is the founder of Rebar Interactive, a digital marketing and patient recruitment company serving the clinical trial industry. She manages the development and implementation of digital strategies designed to meet patient enrollment, as well as other goals. Prior to her current role, Rahlyn was a clinical research coordinator for five years.

10:30 a.m. to 10:45 a.m. – Morning Refreshment & Networking Break

10:45 a.m. to 1:15 p.m. – PRE-CONFERENCE MORNING WORKSHOP B

Refreshments will be provided during this session.

How To Use Smartphones And Tablets To Ease The Pain Of Patient Reported Outcomes

The importance of patient reported outcomes has increased, driven by regulators and the need to support reimbursement for marketed therapies. Getting timely, accurate information directly from patients has been a challenge, hampered by the unreliability of data recorded on paper and the expense and/or hassle of using single-purpose electronic devices that must be custom programmed.

The increased use of smartphones and tablets, and the apps they enable, offers an opportunity to connect directly with patients about their experiences with therapies being studied in clinical trials and those that are already approved.

This workshop will give you the opportunity to experience and understand what a patient might experience when participating in a study using an iPad and an app.

Through this simulated activity/group session, "Patients" will be assigned to "Investigator Sites" where they will be registered to participate in a study and then provided access to an app via an iPad. Mimicking a visit to the investigator, the "Patient" will set up a unique user account in the app and then respond to questions defined in the study protocol. In Internet time, that data will become part of the study data, available for review, reporting, export and analysis. Data from all workshop "Patients" will be reviewed and action plans defined as necessary.

Also, you will hear and discuss the advantages and challenges presented by this new paradigm, including:

- The concept of BYOD (bring your own device)
- Issues of data security and patient privacy
- Multi-language support
- Use of validated psychometric instruments.
- The user experience, the opportunities and challenges posed in collecting data directly from patients using apps on smartphone and tablets.

WORKSHOP LEADER: Anne Zielinski, is The Global Lead, Patient Cloud at Medidata Solutions. For over fifteen years Anne has led efforts to streamline clinical trials using technology. Her current focus is enabling patients' voices to be more easily heard in clinical research.

1:15 p.m. to 2:00 p.m. – Lunch On Your Own -- But Not Alone!

2:00 p.m. to 4:30 p.m. – PRE-CONFERENCE AFTERNOON WORKSHOP C

How To Integrate The Right Mix Of New Media Tools To Maximize Study Participation, Ensure Compliance & Mitigate Risk

We all know that patient recruitment isn't just about "recruiting a study participant" but it's also inclusive of ensuring compliance and high retention rates that optimize data for the Sponsor.

Our industry has evolved over the past decade to introduce and accept many new ways of thinking for both engaging study participants in the beginning and managing them more successfully through the study. These include, but are not limited to: social media, community outreach and public relations, use of site networks, clinical call centers, debit card payment systems, text-based correspondence and even e-consents. This workshop will take a look at these various tools and discuss how utilizing the right mix of these can mitigate risk for the Sponsor, maximize data and control study budgets. While these are the benefits for the Sponsor, these technologies also drive value of convenience, education, simplicity and engagement for the study participant as well.

In this interactive session, you will learn how to:

- Embrace innovation, engage various providers
- Utilize various new media/technologies
- Properly assess the study population
- Implement an effective blend of these systems; there is no one size fits all

WORKSHOP LEADER: Garrett Smith, Vice President of Business Development & Marketing at Accelovance. Mr. Smith has been in the clinical research space for nearly a decade, starting his career in patient recruitment and clinical site support solutions. During this time, he has had direct involvement in patient recruitment strategy and implementation, clinical site operations and CRO/study management experience.

"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, - 400BC**

General Sessions - Day One - Tuesday, December 10, 2013

8:00 a.m.
Registration & Continental Breakfast

8:30 a.m. SPEED NETWORKING-WELCOME

Chairperson's Welcome & Speed Networking

This fun and fast-paced forum is designed to provide you with a unique and fun opportunity to share your goals for this conference while getting to know your fellow conference attendees and their most pressing concerns.

David Heck, Business Development Director, Life Sciences
LIONBRIDGE LIFE SCIENCES
Conference Chairperson

9:00 a.m. CASE STUDY

Collaborating with Patient Advocacy Groups to Increase Enrollment in Rare Disease Clinical Trials

BioMarin partners with rare disease patient advocacy groups to increase awareness of and participation in clinical trials. Determining which advocacy groups to partner with and the extent of involvement is critical.

Case studies will be discussed on ways to incorporate patient voices throughout the drug development process, including online listening projects and patient advisory boards. In addition, a case study on the use of social media to increase recruitment and discussion of the study among the patient community will be described.

You will leave this session with new ideas on how to effectively collaborate with patient advocacy groups by:

- Identifying ways to build and maintain powerful partnerships with patient advocacy groups.
- Understand what patients are communicating about through listening projects
- Identifying ways to use social media to increase awareness and trial participation

Kim Mooney, MS, CGC Manager, Patient Adv.
BIOMARIN PHARMACEUTICAL, INC.

9:30 a.m. Q & A SESSION

Idea Exchange: Questions, Feedback, Collaboration

9:35 a.m. CASE STUDY

Strategies for Cost Effective and Efficient Patient Recruitment

Traditional media has been overshadowed by new and more cost effective digital strategies for patient recruitment. The question of how to spend your media budget to get the most qualified potential patients remains and has become even more complicated with the introduction of cutting edge digital and mobile technologies . How can you build a successful, engaging media plan to save time and money on patient recruitment?

Through real-life application, you will learn strategies and approaches to help you:

- Understand digital media and how to use it effectively to target patients for your trial
- Use Traditional media as a compliment, not a definitive solution

- Track media campaigns for optimization and effective ROI

Leslie Kipke- Ives Sr. Manager Patient Recruitment Services
PPD, INC.

10:05 a.m. **Q & A SESSION**
Idea Exchange: Questions, Feedback, Collaboration

10:10 a.m.
Morning Refreshment & Networking Break

10:20 a.m. **GROUP EXCERCISE**
Patient Engagement For Clinical Trials: Common Challenges and Peer-to-Peer Advice

This is your chance to discuss with fellow attendees and speakers what your most pressing engagement, recruitment, and retention concerns are in clinical trials and what solutions you hope to gain during this training. We will address the group's list of issues and questions throughout the conference. All participants will be encouraged to contribute to the discussions connecting and collaborating on hot topics around patient centricity.

10:50 a.m. **CASE STUDY**
How to Leverage Clinical Trial Matching Technology to Increase Patient Awareness and Enrollment in Clinical Trials

BresatCancerTrials.org (BCT) was inspired by two breast cancer patients who in 1998 wanted to consider clinical trials as an option for care but were not referred by their oncologists. They were "engaged, empowered, and equipped," but unlike today's e-patients, frustrated by the absence of online resources available for health consumers. Thus was born BCT: an online clinical trial matching service for independent trial seekers like themselves.

Developed in collaboration with UCSF and NCI, BCT was successfully evaluated as a Bay Area research pilot and then launched as a non-profit, nationwide service in 2008. In addition to trial matching, BCT provides consumer-friendly trial summaries and a Trial Alert Service that notifies users whenever new studies match their situation. It currently lists over 500 breast cancer research studies and attracts over 6000 visitors a month.

Over the past 5 years, BCT continues to add content, improve navigation, and add features designed to broaden outreach. In this session, you will hear lessons learned from operating BCT as a consumer-oriented clinical trial matching service and the potential for adapting its underlying CTMatch technology for use in other settings and disease domains.

This patient-centric initiative will share the latest strategies for:

- Patient engagement: from consideration of trials to enrollment
- Overcoming barriers that prevent BCT users from enrolling in trials
- Designing a user-friendly navigator Portal for facilitated access to BCT
- Ensuring adaptability of CTMatch technology beyond breast cancer

Elly Cohen, Assistant Professor, Program Director, BreastCancerTrials.org
UCSF

11:20 a.m. **Q & A SESSION**
Idea Exchange: Questions, Feedback, Collaboration

11:25 a.m.

Morning Refreshment & Networking Break

11:35 p.m. CASE STUDY

Leveraging Patient Communities for Clinical Trial Recruitment

Patients with specific medical conditions often band together online for information and support. Learn ways that clinical trial recruiters are leveraging such communities to attract patients to clinical trials via an examination of:

- Advantages of leveraging 3rd party pre-existing condition-specific communities versus creating and managing online communities on your own
- Options to effectively reach communities of patients:
  - Online
  - At the Pharmacy
  - Via Physician's Offices
- Pros and Cons of database strategies versus just-in-time recruitment
- Patient perspectives on the value of clinical trials and the appropriateness of marketing them.

Dennis Upah, Executive Vice President, Enterprise Markets
REMEDY HEALTH MEDIA

Ann Bartlett, Diabetes Patient Expert
HEALTHCENTRAL.COM

12:05 p.m. Q & A SESSION

Idea Exchange: Questions, Feedback, Collaboration

12:15 p.m.

Lunch On Your Own -- But Not Alone!

Join a group of your colleagues for lunch with an informal discussion based on a patient engagement hot topic. Take this opportunity to join others in a small, interactive group setting to network and brainstorm solutions to your most pressing patient engagement, recruitment and retention concerns.

1:45 p.m. CASE STUDY

How Integrating Patient Advocates into the Research Continuum Will Expedite Clinical Trials and Bend the Cost Curve Down

Ninety-four percent of patients told survey researchers at ResearchAmerica that their physicians never recommended a clinical trial to them. It is no wonder that clinical trials accrue between one percent and five percent of patients, depending on the therapeutic indication. Unless we can come up with strategies to expedite patient entry into clinical trials, the pipeline--which would otherwise be robust and productive--will be jeopardized.

Patient advocates can help and not hinder the biopharmaceutical industry by being integrated at every rung of the research continuum--from protocol design committees where we can help sponsors enhance and expedite patient participation in clinical studies while:

- Reducing "Screen Fails"
- Increasing patient compliance and medication adherence
- Decreasing the numbers of patients “Lost To Follow-up” due to disclosed clinical trial results in a fashion that is understandable to pharma’s target patient population

This session will explore how patients and patient advocates can benefit pharma's bottom line by:

- Integrating their voices into the drug pipeline from the very beginnings of protocol design meetings to drafting clinical trial results
- Navigating molecular profiling and sequencing results for patients in order to best identify relevant clinical trials
- Advocating the reimbursement of molecular diagnostics and novel therapeutics

Marcia K. Horn, President and CEO
(ICAN) INTERNATIONAL CANCER ADVOCACY NETWORK

2:15 p.m. **Q & A SESSION**

Idea Exchange: Questions, Feedback, Collaboration

2:20 p.m. **CASE STUDY**

How to Improve Subject Retention and Accuracy of Data for 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. Consideration must be made with the patient population that is targeted and how the ePRO tools may be used to enhance subject retention. 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 share key criteria for utilization of ePRO in a trial and patient considerations, including:

- Pointers for discussion items and decisions to be considered
- Engagement of the sites for using the ePRO in a clinical setting
- Criteria for adopting ClinRO in clinical trials and the advantages and disadvantages
- Potential impact on budgets and resourcing using ePRO and ClinRO

Elizabeth Kurkimilis, Senior Clinical Operations Manager
CELGENE

2:50 p.m. **Q & A SESSION**

Idea Exchange: Questions, Feedback, Collaboration

2:55 p.m.

Afternoon Refreshment & Networking Break

3:05 p.m. **CASE STUDY**

epharmasolutions
Technology-driven clinical trial solutions

Collaboration For Patient Enrollment To Optimize Patient Recruitment Spending

Only 6% of patients that respond to a recruitment advertisement end up enrolling into the study – for many reasons. Unfortunately, the industry loses 94% of these highly motivated patients due to a lack of technology to match those patients to other trials that sponsor is conducting.

This session will review the Referral Plus™ program that programmatically matches patients who disqualify from one study to others they may qualify for using a proprietary geo-therapeutic matching algorithm.

The ReferralPlus program has expanded into an industry-wide collaboration of over 20 pharmaceutical companies and CROs to help optimize patient recruitment spend while improving the chances for patients to find studies they qualify for.

The Referral Plus™ program provides:

- Sponsors an opportunity to leverage patient recruitment budgets across multiple studies
- Patients a much higher probability of qualifying for a study
- Sites additional options to provide to patients

Case studies from the original three pilots will be presented showing significant reductions in cost per randomized patient and cycle times.

Lisa LaLuna, Sr. VP, Corporate Development & Innovation
ePHARMASOLUTIONS

3:35 p.m. **CASE STUDY**

HUDSONGLOBAL

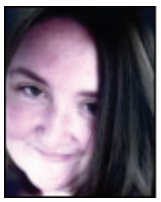
Building a Bridge between Central Recruitment and Your Sites for Optimal Patient Engagement

Sponsors invest a good deal of time, effort and resources into the selection of sites and yet it's a common meme in the industry to expect failure in more than half. In fact, fifty percent of clinical research sites enroll one or no patients in their studies. (Pierre, "Recruitment and Retention". 2006) To supplement these efforts, sponsors turn to centralized recruitment and retention providers to fill in the gaps and accelerate enrollment. But is this model working? Not often. The current model is broken, pitting centralized recruitment and retention one-size-fits-all strategies against the sites in an unhealthy competition to claim patient accruals.

There is a better way. In this presentation, you will examine how early planning and coordination between sites, sponsors, and the CRO can shift the model to one that embraces clear responsibilities and shared goals to reduce site failure and improve patient engagement for optimal recruitment and retention.

In this session, you will learn how to:

- Embrace a "no site left behind" mentality that encourages proactivity vs. contingency planning
- Employ a new model for providing holistic centralized support
- Harness the unique strengths of sites and central recruitment vendors to optimize enrollment timelines and eliminate wasteful overlap in budgets
- Eliminate competition between central support and your sites to shift focus where it belongs: the patient



Angela Radcliffe, VP, Director Clinical Trials
HUDSON GLOBAL

Deborah Tyler,
Senior Clinical Study Manager
TAKEDA DEVELOPMENT CENTERS AMERICA, INC.

4:05 p.m. Q & A SESSION

Idea Exchange: Questions, Feedback, Collaboration

4:10 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

4:40 p.m. Q & A SESSION

Idea Exchange: Questions, Feedback, Collaboration

4:45 p.m. CASE STUDY

How To Identify, Enroll and Retain Patients with Chronic Conditions

As the Baby Boomer population comes into the retirement age and our population increases in longevity, a greater number of patients are being diagnosed with chronic conditions such as Hepatitis C, diabetes, arthritis, and heart disease. The pharmaceutical and biotech industries are working diligently on a number of clinical trials to improve treatment regimens for these and other chronic conditions and as a result, researchers are being called upon shift their thinking and create unique and effective patient-centric engagement and education tools to deliver to this ever-growing population throughout the duration of clinical trial process and beyond.

Through this session you will discover approaches to assist you with:

- Strategies for identification and engagement of your target patient population to ensure bolus recruitment
- Overcoming barriers to patient compliance and medication adherence
- Tips for creating effective retention plans

Jennifer Melione, Global Trial Optimization Specialist
MERCK

5:15 p.m.
Day One Wrap Up

5:30 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 - Wednesday, December 11, 2013

RAVE REVIEWS FROM PAST PHARMA AND HEALTHCARE CONFERENCE ATTENDEES:

"It was great to hear what others are doing and to finally realize what we need to do to get started. It seems so simple now; that I wonder what was really holding us back. This conference helped us solidify our plan."
D. King, Application Support & Web Manager
ATLANTIC HEALTH

"I came to get some case studies from leading companies that I could take back and relay to others to get social media started at our department statewide. I feel much more prepared to do this and my expectations are grounded in reality instead of theory."
S. Palmer, Director, Communications and Health Marketing
ALABAMA DEPARTMENT OF PUBLIC HEALTH

8:00 a.m.
Continental Breakfast & Networking

8:30 a.m.
Opening of Day Two

8:40 a.m. CASE STUDY
"Mobilizing" the Recruitment Funnel For Improved Results

Mobile phones have become a staple in our patients' lives, but they are a relative rarity in research studies. The mobile phone offers unprecedented access to engage patients, recruit them to studies and retain them throughout the entire study. Sites, Sponsors and Subjects who have used this technology give rave reviews and have seen amazing results on their studies.

Omniscience Mobile and Parexel have teamed on multiple studies to bring modern technologies to the recruitment field. This session will demonstrate how text messaging can significantly improve the response levels to traditional patient recruitment advertising. Furthermore, this session will address options to deal with "study fatigue" and poor "pull through" at the site level. This pragmatic session will help you understand:

- Why Mobile Phone technologies are essential to your research study
- Exactly how text messaging is incorporated in patient recruitment advertising
- How to track ROI, as well as the results seen from previous studies
- How to track whether a site is actively following up on referrals generated through centralized programs
- Best practices in tracking referrals all the way through randomization and completion

Mobile technologies are fun and offer exciting ways to communicate with our patients. Come learn how you can add this tool to your studies and see immediate benefits! Bring your phone, as this will be an interactive session!

Jeff Lee, CEO
OMNISCIENCE MOBILE

Brendan O'Neill, Director, Patient Recruiting Strategy Group
PAREXEL

9:10 a.m. Q & A SESSION
Idea Exchange: Questions, Feedback, Collaboration

9:15 a.m. CASE STUDY
Addressing Diversity In Designing Clinical Trials To Improve Outcomes

Addressing diversity in clinical studies is a key factor to understand and improve individual patient outcomes. Barriers for enrollment of minority patients should be taken into account when planning clinical studies in order to reduce under representation of diverse racial/ethnic populations. Sponsors and investigators need to work collaboratively in developing innovative approaches to improve individual outcomes for all patients.

You will leave this session with new ideas to help you engage a diverse population, including:

- The business drivers for inclusion of minority patients in clinical trials
- Understanding barriers to increase enrollment of minority patients in clinical trials
- Implementing activities to create a more effective approach for enrolling minority patients in clinical trials

Gerson Peltz, MD, MPH, Medical Director, Global Pharmacovigilance & Epidemiology
BRISTOL-MYERS SQUIBB

9:45 a.m. **Q & A SESSION**

Idea Exchange: Questions, Feedback, Collaboration

9:50 a.m. **CASE STUDY**

How To Recruit Patients From "The Cloud": Identifying The Most Appropriate Social Media Tools For Your Trial and Staying Within The Current Regulatory Guidance on Using Social Media Tools

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. However, it has been estimated that less than 5% of the ePatients know anything about clinical trials. This is compounded by the lack of tested policies and procedures within the sponsor organizations, leaving the clinical project manager with many challenges when trying to access this valuable pool of potential trial participants.

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 some recent examples of social media as a platform to enhance recruitment strategies. Examining each step – from vendor selection through program implementation – you'll gain a greater understanding of the impact and potential roadblocks that may occur. You'll also learn tips for success in your own e-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, M.Sc., MBA, Director, Project Management & Quality Systems
NUTRASOURCE

10:20 a.m. **Q & A SESSION**

Idea Exchange: Questions, Feedback, Collaboration

10:25 a.m.

Morning Refreshment & Networking Break

10:35 a.m. CASE STUDY

The Science Behind Recruitment and Retention: How To Use An Evidence-Based Behavioral Model To Develop A Patient-Centric Communications Plan

In the competitive landscape of clinical research, it's critical to have deep knowledge of the patients you are seeking to recruit. To accomplish this, an analysis of the patient journey can serve as a foundation to drive patient engagement, ensuring successful recruitment and retention. Insights gained from the patient journey are translated into actionable recommendations using an evidence-based behavioral model. This approach puts patients at the center of the recruitment plan, by first identifying key patient insights, and then using these insights to develop a communication plan that resonates.

During this session, you will:

- Experience how a behavioral science-based framework for communications planning can bring patients into trials more effectively
- Understand how to create lasting relationships with patients throughout the trial's duration
- Gain a new perspective on putting the patient at the center of the recruitment plan

Jim Kremidas, Principal, Independent Consultant
KREMIDAS CONSULTING

11:05 a.m. INTERACTIVE PANEL

Engaging Patients & Changing Behaviors – Live Panel Reaction

Online user generated content has become one of the most trusted and engaging resources within the digital patient education ecosystem. The WEGO Health Behavioral Intent Survey reveals the impact of community created content; tracking the path and impact of social recommendations from Consumer Opinion Leaders (aka Health Activists) to their followers.

This findings presentation and panel discussion will uncover:

- The types of content that empowers patients and changes behaviors
- The needs of today's most active online communities and their leaders
- How organizations can leverage community content to engage and recruit patients

Panelists Include:

Aaron Blocker, Crohn's and IBD Health Activist & creator of the **LIFE TAKES GUTS** organization, @LifeTakesGuts

Erin Smith, Celiac Health Activist & blogger of **GLUTEN FREE FUN**, @gfreefun

Jordan Davidson, Endometriosis and Chronic Illness Health Activist & Co-founder of the **ENDOWARRIORS**, @endowarriors

Facilitator: Bob Brooks, EVP
WEGO HEALTH

11:35 a.m. Q & A SESSION

Idea Exchange: Questions, Feedback, Collaboration

11:40 a.m. CASE STUDY

Think Local for Global Recruitment

Lionbridge LIFE SCIENCES

One size does not fit all when it comes to engaging potential study volunteers for a global clinical trial. You have to adapt your technique and material to the audience you want to engage.

The importance of understanding cultural differences is key to creating improved recruitment materials and campaigns. Communications created with a Western bias cannot be expected to succeed in different cultures. Initiatives undertaken with insufficient knowledge of local cultures are likely to create recruitment delays.

Words, metaphors, and images that are easily understood in North America often fail in global cultures where social and cultural attributes may differ substantially. Even something as seemingly insignificant as a model wearing a color deemed inappropriate by the local population can derail a campaign and delay a trial.

Status quo solutions for patient recruitment in clinical trials may have been all that was possible at one time, but are now increasingly deficient in terms of quality, risk, consistency and results.

The presentation focuses on cultural considerations and Transcreation - the process of creating messages that resonate across local markets.

David Heck, Business Development Director, Life Sciences
LIONBRIDGE LIFE SCIENCES

12:10 p.m.

Lunch On Your Own -- But Not Alone!

Join a group of your colleagues for lunch with an informal discussion based on a patient engagement hot topic. Take this opportunity to join others in a small, interactive group setting to network and brainstorm solutions to your most pressing patient engagement, recruitment and retention concerns.

1:15 p.m. GROUP EXERCISE

Patient Engagement For Clinical Trials: Common Challenges and Solutions

This follow up “round-table” exercise will explore a variety of tactics in improving patient engagement, recruitment, and retention. The challenges and questions of clinical trials are many, but this “group-think” will leverage the experience and knowledge of all attendees and participants to help identify solutions.

1:45 p.m. CASE STUDY

Innovate Study Designs by Engaging Patients Directly for Research

QUINTILES

The research landscape has changed. Patients are more connected than ever and eager to participate in research. However, as many as of 90% of them will never be approached to participate in a clinical study. “Dr. Google” is now the most visited “physician.”

As the landscape has changed -- including constraints such as reduced budgets, shortened timelines and increased need for more real-world data -- we must look for novel approaches to gain the data we need.

Quintiles' Digital Patient Unit (DPU) has been innovating in this space to develop solutions for our customers to prosper in this new digitally connected landscape. This session will explore case studies for several novel, direct-to-patient designs:

- Insight collection from patients to support better protocol design and study strategy
- Direct-to-patient studies that collect and integrate patient reported outcomes, EMR data and other data elements

- Virtual usage in Phase 2/3 studies
- Engaging with our global patient communities of 3.1 million patients in seven countries

John Reites, Director, Operations-Digital Patient Unit
QUINTILES

2:15 p.m. **Q & A SESSION**

Idea Exchange: Questions, Feedback, Collaboration

2:20 p.m. **CASE STUDY**

How To Quantify Patient Engagement Return On Investment: Cardiovascular Outcomes Study for Gout, Control vs. Test Group

This session examines a Top 10 sponsor's analysis of IVRS data comparing the attrition rates of patients who were exposed to patient engagement techniques and those who were not, from a 7,000-patient cardiovascular outcomes study of gout. Using industry-standard clinical trial costing metrics for gout trials, the presenter will also explain how to estimate the cost impact of patient attrition for both the control and test groups to help quantify patient engagement return on investment.

In this session, you will learn how to:

- Assess the impact of patient engagement techniques on reducing patient attrition in clinical trials
- Estimate the cost savings of reducing patient attrition for clinical endpoint studies

Scott H. Connor, Vice President, Marketing
ACURIAN, INC.

2:50 p.m. **Q & A SESSION**

Idea Exchange: Questions, Feedback, Collaboration

2:55 p.m. **INTERACTIVE PANEL**

INTERACTIVE PANEL: Hot Topics In Personalized Medicine

From NICE's rejection of Xalkori to the latest from CMS, we end 2013 with overarching issues revolving around personalized medicine that affect every therapeutic space and every player in the field--from patient, to advocate, to scientist, to clinician and every other provider, to industry and regulatory executives, and from government to private payers. Join us as an all-star panel--that is daily "in the trenches" of personalized medicine and molecular diagnostics engages the audience in an interactive session that seeks clarity amidst the clamor and confusion.

Panel Administrator/Leader:

Marcia K. Horn, President & CEO
(ICAN) INTERNATIONAL CANCER ADVOCACY NETWORK

Panelists To Be Anounced Shortly

3:30 p.m. **CHAIRPERSON'S RECAP**

Lionbridge
LIFE SCIENCES

Chairperson's Recap And Close Of General Sessions

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

David Heck, Business Development Director, Life Sciences
LIONBRIDGE

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RAVE REVIEWS FROM PAST PHARMA AND HEALTHCARE CONFERENCE ATTENDEES:

"Timely and topical – all the presentations provided complimentary perspectives on social media."
M. Hudson, Senior Communications Executive
PUBLIC HEALTH AGENCY OF CANADA

ALL CONFERENCE SESSIONS WILL BE HELD AT THE:

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Click on the following link: http://www.amanet.org/exec_conf_cntr/new_york/hotels.htm or contact the hotels below directly.
Note: We recommend that reservations be made early, as the number of rooms at preferred rates is limited and don't forget to mention you are attending a conference at the AMA Conference Center for the special rates!

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Join us in New York City at The Patient Engagement For Clinical Trials: Best Practices For Recruitment & Retention Using Patient-Centric Initiatives - December 9-11, 2013. Enjoy this wonderful city's restaurants, shopping, attractions and nightlife!

For more information on your visit to New York City, go to http://www.nycgo.com/.

REGISTRATION FEES:

The following are included in your conference registration: attendance, a detailed conference workbook and any additional meeting materials -- including access to the conference wiki (includes electronic copies of presentation materials), 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 **November 8**	**Regular Pricing:** Register with payment after **November 8**
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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.

SPONSORSHIP & EXHIBIT OPPORTUNITIES ARE AVAILABLE:

This conference provides an excellent opportunity to market your products and services to a targeted clinical trials audience. Space is limited, so please call Angie at (773) 695-9400 ext 222, for more information.

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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 November 25th)** a refund will be provided less a $295 administration fee. Registered delegates who do not attend or who cancel two weeks prior to the conference or less **(on or after November 25th)** 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.

RAVE REVIEWS FROM PAST PHARMA AND HEALTHCARE CONFERENCE ATTENDEES:

"Outstanding! One of the most amazing conferences I have attended in a while."
A. Kaszowski, Web Producer
ST. JOSEPH'S HEALTH CARE, LONDON, ONTARIO

"Overall, there were very interesting presentations!"
S. Lecour, Policy & Program Advisor
HEALTH CANADA

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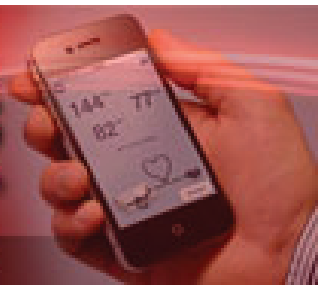

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Please photocopy for group members.

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☐ **Pre-Conference Morning Workshop B**: How To Use Smartphones And Tablets To Ease The Pain Of Patient Reported Outcomes

☐ **Pre-Conference Afternoon Workshop C**: How To Integrate The Right Mix Of New Media Tools To Maximize Study Participation, Ensure Compliance, & Mitigate Risk

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