Addressing how sponsors of clinical trials can realistically partner with patients and how patients can partner with sponsors.

March 3 - 4, 2014          The Rittenhouse          Philadelphia, PA

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Dear Attendees,

Sponsors have a greater than ever commitment to partner with patients, but the reality is there are limitations and barriers – such as HIPAA, to name just one of many. What are some of the best strategies, programs, technologies and ideas to overcome the limitations and barriers?

We are delighted to present Patients as Partners with industry, advocacy, academia, patients and the FDA. Together, they address the latest strategies, technologies and policies to vastly improve the patient experience in clinical trials.

Patients as Partners takes a broad view of the patient experience and how we engage with patients across the entire clinical trial continuum. This includes early research, patient-centric protocol design, recruitment, retention, engagement, and communicating results with patients acting as ambassadors and educators. Ask questions, network and make the most of your conference experience. Huge thanks to our speaking faculty, advisors and sponsors. I am inspired by their commitment to patient engagement excellence!

Best wishes,

Valerie Bowling
Executive Director

THECONFERENCEFORUM.org
8:00 AM
Registration & Breakfast
Grand Salon, 2nd Floor

8:30 AM
Co-Chairs’ Welcome
Grand Ballroom, 2nd Floor
David W. Coman, MBA
SVP, Quintiles Health Engagement and Communications
Ken Getz, MBA
Director of Sponsored Research, Tufts CSDD and Founder, CISCRP

8:35 AM
State of Industry Address on the Pharma-Patient Relationship: How Good Are We at Engaging Patients?

- Review metrics on recruitment and retention effectiveness
- Discuss root causes of poor enrollment performance
- Identify opportunities to optimize recruitment and retention
- Explore a comprehensive model and solutions to engage the public and patients as partners

Ken Getz, MBA
Director of Sponsored Research, Tufts CSDD and Founder, CISCRP

9:15 AM
Patient Point of View on the Clinical Trial Experience

Both the design of clinical trials and our relationship with patients have to change to not only attract and retain patients for better quality data, but also to keep up with evolving science, i.e., personalized medicine.

The purpose of this session is to provide live feedback from a panel of clinical trial participants to help you gain a much better understanding of the patient perspective on their experience in clinical trials. How can this feedback help you design and execute a more successful trial?

Discussion points include:

- Patient Awareness: How did you find out about the trial? How was it presented? Were there any uncertainties or reservations? Why did you agree to participate?
- Patient Enrollment Process: Ease of Process, Consent Forms, Time Commitment. Were all your questions answered at enrollment?
- Clinical Management: Quality of Care, Health Team Involvement
- Quality of Life: Impact on ADL’s, Outcome Measurement Tools. Overall level of satisfaction: would you recommend or refer it?
- Additional thoughts on trial participation

Moderated by:
Ken Getz, MBA
Director of Sponsored Research, Tufts CSDD and Founder, CISCRP

With Patient Panel including:
Iris Culbert
Senior Clinical Project Manager, Global Clinical Operations, Teva Pharmaceuticals
Matilda E.V. Gogos
Patient Representative
Sterling (Skip) Ivison
Patient Representative
Linda Morgan
Patient Representative
Margo Rosenblatt
Patient Representative

10:00 AM
Sites’ POV on Partnering with Patients (or Lack Thereof)

Sponsors have a greater commitment than ever to partner with patients through stronger collaborations with sites. However, the reality is far more difficult than some may fully understand. During this panel, we discuss some of these limitations and what all stakeholders must do to change the current reality of only 5% of the general public making the decision to participate in clinical trials. To truly partner with patients, it is crucial that all stakeholders understand what struggles and limitations the sites have in creating partnerships with patients. This session allows us to hear the Sites’ POV.
Moderated by:
Christine Pierre
President, Society for Clinical Research Sites

With:
Deena Bernstein, MHS
Director Clinical Research, Sheridan Clinical Research, Inc.
Dianne T. Edwards
Director, Clinical Trials, Reading Hospital and Health System
Jane Lettman
Regional Site Director, RxTrials, Inc.
Fabian Sandoval, MD
Pediatric Research Director/ Investigator, Inova Health System

10:45 am
Networking Break
Grand Salon, 2nd Floor

11:15 am
Sanofi on Developing a Truly Patient-Centric Research & Development Practice: Pre-Clinical to Late Stage Development

- How Sanofi effectively collaborates with patients in the pre-clinical space
- Collaborating with patients to develop clinical trial protocols and supporting activities through to Phase III
- A systematic and holistic approach to patient engagement: the Sanofi Patient Engagement Initiative

Victoria Dibiaso
Head of Investigator & Patient Networks, Sanofi
Anthony Yanni, MD, MBA
Head of Patient Value & Strategy, Sanofi

12:00 Noon
Six Degrees of Kevin Bacon

Lasting relationships with patient advocacy and community groups can be an important part of a patient recruitment program. The question is, how do you build those relationships? And once you’ve built them, how do you maintain them? Aaron Fleishman from BBK Worldwide will discuss several ways you can work with advocacy groups as a patient recruitment tactic.

Aaron B. Fleishman
Director Social Innovation and Advocacy Engagement, BBK Worldwide

12:20 PM
Developing Protocols with the Patient

Nothing affects the patient’s experience as much as the protocol design. In this session, we address:

- How to involve the patient in protocol design
- How do we incorporate patient ideas into the protocol?
- What do we need to do with the protocol design to greatly enhance the patient’s experience?
- The role of crowdsourcing in obtaining the patient’s voice
- How can patient advocacy groups help with protocol design?
- Engaging investigative site staff in protocol design
- Different ways trained advocates can get involved in clinical trials
- How can study funders influence patient engagement
- Case example of NBCC and BioMarin on partnering together for protocol design

Moderator:
David W. Coman, MBA
SVP, Quintiles Health Engagement and Communications

Panelists:
Annette Bar-Cohen, MA, MPH
Executive Director, Center for NBCC Advocacy Training, National Breast Cancer Coalition
Lily Cappelletti
Associate Director, Research Partnerships, The Michael J. Fox Foundation for Parkinson’s Research
Debra Lounsbury, RN, MS
Principal Scientist, Oncology Clinical Sciences, BioMarin Pharmaceutical Inc.
Tomasz Sablinski, MD, PhD
Founder & CEO, Transparency Life Sciences

1:00 PM
Luncheon
Grand Salon, 2nd Floor for Buffet
2:00 PM

Interview Series
Greg Simon
CEO Polliwog

2:05 PM

Michael J. Fox Institute’s PPMI Study: Wildly Successful Recruitment and Retention With A Patient-Centric Approach

In 2010, The Michael J. Fox Institute started recruiting patients for the Parkinson’s Progression Markers Initiative, a 55 million dollar foundation-funded and -sponsored biomarker study. They recruited 400 newly diagnosed Parkinson’s patients and 200 volunteers. The Fox team went to all 24 sites and let the patients ask questions about study. The end result was 683 subjects and only 18 withdrew. In this interview, learn from this case example on how to replicate the success of this study.

Lama Chahine, MD
Instructor of Neurology, Parkinson’s Disease and Movement Disorders Center, University of Pennsylvania

2:20 PM

A Remote Clinical Study with Genentech: The Trial-In- A-Box

With the FlubGon Case Study that is done at the patient’s home, the paradigm has shifted for patient convenience and accessibility with better engagement, tools and data. Komathi Stem discusses how Genentech partnered with the patient in this wonderful example.

Komathi Stem
Senior Director, Product Development, Innovation Lead, Genentech

2:35 PM

The Facebook Trial at UCSF: Re-Thinking the Patient Experience and Engagement Model

A smoking cessation study in adolescents was done entirely through Facebook at UCSF. Nariman Nasser speaks on taking the patient perspective into account, making the study easy and accessible for patients to participate, helping people stay committed.

Nariman Nasser
Digital Strategist, Genentech (Formerly Senior Director, Participant Recruitment & Study Management Services, UCSF Clinical & Translational Science Institute)

2:50 PM

Clinical Trials Transformation Initiative: Increasing the Quality & Efficiency of Clinical Trials

The Clinical Trials Transformation Initiative is a public-private partnership established by the FDA and Duke University to identify and promote practices that will increase the quality and efficiency of clinical trials. In this session, hear from leaders of three of their initiatives on the innovative methods they’re implementing for personalizing the patient experience.

• Patient Leadership Council
• Recruitment & Retention project
• Best Practices for Effective Engagement with Patient Groups Around Clinical Trials

Pamela Tenaerts, MD, MBA
Executive Director, Clinical Trials Transformation Initiative
Bray Patrick-Lake, BS, MFS
Director of Stakeholder Engagement, Clinical Trials Transformation Initiative
Ronnie Todaro
Vice President, National Programs, Parkinson’s Disease Foundation and Co-Chair, CTTI Patient Leadership Council

3:05 PM

Millennium’s Online Pyramid Trial

Millennium discusses their study-specific strategy and campaign for a Diffuse Large B-Cell Lymphoma study that led to patient recruitment numbers going up dramatically.

Maria Corvez
Clinical Research Manager II, Millennium Pharmaceuticals
3:20 PM

**Eli Lilly’s Site and Patient Simulation Initiative for All Disease States**

Eli Lilly will share the updates on their new site and patient simulation initiative. They are quickly moving this patient-centric approach to a method or process across all disease states at the company.

_Daniel Davis_
Oncology Business Unit Advisor, Eli Lilly

3:35 PM

**What We Can Learn from the Restaurant Business in How We Manage Patients**

- Restaurant analogy
- Cultural change management
- Technical and emotional components
- How to make the cultural shift

_Susan Salgado, PhD_
Managing Partner
Hospitality Quotient

3:50 PM

**Networking Break**

4:05 PM

**Innovative Recruitment Initiatives: Fox Trial Finder & CISCRP’s Referral Plus Initiative**

Michael J. Fox and CISCRP discuss their robust and patient-friendly tools that match patients to specific studies for Parkinson’s and identify trials for patients that are ineligible for another study.

_Lily Cappelletti_
Associate Director, Research Partnerships,
The Michael J. Fox Foundation for Parkinson’s Research

_Ken Getz, MBA_
Director of Sponsored Research, Tufts CSDD
and Founder, CISCRP

4:30 PM

**Innovative Technologies for Patients in Clinical Trials**

This session showcases innovative technologies for patients in clinical trials in an “American Idol” format. Our panel of judges will listen to the rapid-fire presentations and provide feedback to each presenter. It is an opportunity for the audience to hear how industry peers probe and get to the core of how the technologies or services can benefit the partnership between patients and sponsors.

**Presenting Companies:**

- **MMG**
  Helen West
  VP Strategic Development

- **Artcraft Health**
  Marc Sirockman
  EVP – General Manager

- **CureLauncher**
  Stephen J. Goldner, JD RAC
  Chairman and CEO

**Judges:**

- **Jacqueline Cole**
  Clinical Operations Portfolio Management, Oncology, Eli Lilly

- **Maria Corvez**
  Clinical Research Manager II, Millennium Pharmaceuticals

- **Daniel Davis**
  Oncology Business Unit Advisor, Eli Lilly

- **Komathi Stem**
  Senior Director, Product Development, Innovation Lead, Genentech

5:30 PM

**Reception**

Grand Salon, 2nd Floor
8:00 AM
Breakfast
Grand Salon, 2nd Floor

8:30 AM
Co-Chairs’ Welcome
David W. Coman, MBA
SVP, Quintiles Health Engagement and Communications
Ken Getz, MBA
Director of Sponsored Research, Tufts CSDD and Founder, CISCRP

8:35 AM
The 5 Habits of Highly Patient-Focused Research: A New Research Experience
As the landscape has changed, new best-in-class patient engagement strategies are changing the way clinical research is conducted – making it more simple, more integrated, more accessible and more patient-minded. This session will explore the 5 habits of highly patient-focused research including Quintiles’ innovative direct-to-patient programs that are helping to shape this new research experience for patients.
John Reites
Senior Director, Offer Development, Quintiles

9:00 AM
The Pfizer Blue Button Project: Engaging Patients by Sharing Electronic Clinical Data
In 2013 Pfizer launched the Pfizer Blue Button Project, a first-of-its-kind initiative enabling patients who have participated in clinical trials the opportunity to download their individual clinical data in a lay language summary of study results. Using the Blue Button standard launched by the White House, patients will be empowered to use the data to improve their overall health and wellness, from sharing with healthcare providers to powering clinical risk assessments. In this session Pfizer will share more on why they have launched this initiative, initial learning, and where the project may go if successful.
Adam Dole
Presidential Innovation Fellow, The White House
Jennifer Wulff
Director, Clinical Innovation, Pfizer

9:40 AM
An Industry Collaboration to Improve Global Enrollment
95% of patients who reply to a recruitment ad do not get into the trial they responded to for a number of reasons. What happens to these patients? In this session, we learn how ReferralPlus helps screen & match those lost patients to other studies they might qualify for in real time, helping reduce recruitment cost and accelerate cycle times.
• ReferralPlus - a collaborative solution
• 20 major life science companies
• Using the same patient screening/matching solution
• Accelerating patient recruitment/retention
• Improving patients’ chances to find studies
Lisa La Luna
SVP of Innovation, ePharma Solutions

10:00 AM
Advances in ePatient-Informed Consent: Are we Ready for an Electronic Consent Process?
The traditional paper-based consenting process is a cumbersome, complex and difficult-to-understand process and informed consent errors are common. In this session, we will provide an overview of the internal and external challenges in setting up a global Electronic Informed Consent pilot and give a flavor of how patients, sites and company are experiencing this novel technology.
• Misconceptions
• Readability
• Benefit/risk, alternate therapies and treatments, requirements, opting out
• Flexibility within study requirements
• Communication
• Breakthrough technologies making the e-consent process far easier
Policy Changes Affecting and Impacting Patients: An Update

Government policy changes directly impact the patient’s experience in areas ranging from protocol design to recruitment to regulatory approval.

- PDUFA V: Patient-Focused Drug Development
- FDA focusing on 20 disease areas and facilitating discussions with patient groups to get information across the spectrum
- Challenges around meaningful endpoints to patient groups
- How industry might incorporate patient perspectives in its product development plans

Kimberly McCleary
Director, Strategic Initiatives, FasterCures

Andrea Tan
Operations Research Analyst, Office of Strategic Programs, CDER, FDA

Taking the Study Visit to the Patients

This session looks at a patient-centric platform that takes a study visit to the patient. By providing convenience to the patient, Gail Adinamis, CEO, GlobalCare Clinical Trials walks us through how this works and results in:

- Faster recruitment
- Lower drop out rates

12:15 PM

Establishing Fair Patient Compensation

- Why is patient compensation an acceptable practice?
- What are the general requirements related to patient compensation?
- Defining what is acceptable vs. what represents undue influence?
- FDA and OHRP guidance related to payment terms
- IRB considerations
- Determining the amount, method and schedule of subject payments

Stuart Horowitz, PhD, MBA
President, Global Professional Services, WIRB Copernicus Group

Rick Ward
VP of Sales, Greenphire

12:45 PM

Luncheon Session: Advances in Post-Study Patient Communication

Engaging patients as partners in the research process: the role of post-trial communication in building public engagement and restoring trust in the research enterprise, with an update on industry commitments and pending regulations.

Communicating trial results effectively: letting patients know how important their participation was; conveying efficacy and safety in simple, everyday language while maintaining scientific accuracy; ensuring strict non-promotionality; and engaging investigative sites.

Case Study: Lilly/CISCRP Pilot Communicating Trial Results Program – successes, challenges and lessons learned from the sponsor perspective.

Jacqueline Cole
Clinical Operations Portfolio Management, Oncology, Eli Lilly

Zachary Hallinan
Director, Patient Communication and Engagement Programs, CISCRP
Luncheon Session: Strategies for Building Post-Trial Patient Ambassadors

Ken Getz explains what patient ambassadors are and what they can do for industry.

- Extending Patient Engagement long after the trial
- Leveraging inactive study volunteers as educators
- Volunteer Alumni programs and other efforts to create a community and continuity after the trial has ended

Ken Getz, MBA
Director of Sponsored Research, Tufts CSDD and Founder, CISCRP
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Quintiles is the largest provider of biopharmaceutical development and commercial outsourcing services with more than 27,000 employees globally. We have helped develop or commercialize all of the top-50 best-selling drugs on the market. Quintiles applies multiple service offerings with extensive therapeutic, scientific, and analytics expertise to help customers navigate an increasingly complex healthcare environment. For more informations, visit www.quintiles.com.

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Artcraft Health Clinical Trials develops innovative solutions to support clinical phases 1 to 4 in the areas of recruitment, enrollment, compliance, adherence, and retention. From print to digital, we communicate the right message, to the right audience, at the right time. Our strategies help you recruit more efficiently and effectively to ensure your trial is a success. For more information, visit www.artcrafthealthed.com/clinical-trials.

CureLauncher solves the clinical trial enrollment problem. It delivers pre-qualified patients for your clinical trials. CureLauncher is a personalized clinical trial matching service that shortens the time to last patient enrolled. Our Relationship Managers have reviewed the criteria with each patient and they are motivated to enroll. For more information, visit www.curelauncher.com.

GlobalCare Clinical Trials, Ltd is the leading global provider of ambulant health care services for clinical trials. GlobalCare provides innovative, GCP-compliant services for biopharmaceutical by conducting selected study visits at locations convenient and comfortable for the patient when travel to the investigator site is not practical. GlobalCare’s traveling clinicians provide patients with a convenient way to participate in trials regardless of study duration, frequency of visits, their disease state or distance to the study site. Additionally, GlobalCare’s patient-centric approach helps to accelerate patient recruitment and improve study patient compliance and retention. For more information, visit www.globalcarect.com.

MMG is a leading, global clinical trial patient recruitment organization. Our recruitment strategists and site specialists have designed and executed successful programs for hundreds of trials across all therapeutic areas. They are supported by our internal resource teams: technology development, call-center, creative materials production, traditional-and-new media, and community-outreach. We maintain best-in-class strategic partnerships that ensure our clients the highest effectiveness in execution, and most-favorable pricing. For more information, visit www.mmgct.com.
Founded in 2009, Mytrus is a California-based clinical technology and services company built on the idea that modern technologies can enable people to safely and effectively participate in clinical trials without requiring them to live near a study center. The company’s proprietary methods can dramatically improve patient recruitment timelines, increase patient retention and reduce overall study costs for sponsors. For more information, visit www.mytrus.com.

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The Healthcare Businesswomen’s Association (HBA) is now in its 4th decade (1977-2007) as a global not-for-profit organization dedicated to furthering the advancement of women in healthcare worldwide. With 15 chapters throughout the US and Europe, the HBA is headquartered in New Jersey with offices in Philadelphia and Research Triangle Park. The HBA provides educational opportunities for women and men to develop cutting edge healthcare industry knowledge and leadership skills. For more information, visit www.hbanet.org.