Designing trials based on patient input offers a glimpse into potential study problems, allowing changes to be made to the protocol and improving overall trial outcomes. The challenge is maintaining the scientific integrity of the trial. How does clinical research find the balance?

Benchmark Against Patient-Centric Design Strategies and Techniques

• Pitch design elements and innovations to a PATIENT SHARK TANK®
• Hear a case study on Actelion’s creation of a patient-reported outcomes tool for rare non-Hodgkin’s Lymphoma
• Examine challenges, risks and benefits of developing an early access program at the onset of a trial
• Utilize site advisory committees to weigh-in on feasibility of protocol elements at the site level
• Consider financial and logistical impacts of trial conduct on adherence in specialized populations

Featuring a Progressive, Hands-On Workshop:
Design Exercise — Collaborate to redesign a protocol, incorporating patient-centric design elements while ensuring the protocol is scientifically sound

REGISTER AT WWW.CBINET.COM/PATIENTCENTRIC • 800-817-8601
Who Should Attend:

You will benefit from attending this event if you are from a bio/pharmaceutical company and have responsibilities or involvement in the following areas:

- Clinical Innovation
- Trial Optimization
- Patient Advocacy
- Patient Engagement
- Clinical Operations

- Protocol/Feasibility Development
- Study Management
- Trial Design
- Patient Recruitment
- Medical Affairs

This conference will also benefit consultants, software providers and companies providing services to the above audience.

The ePatient is here to stay.

Clinical research needs to adapt to the patient, not the other way around. Are you designing trials through the patient lens? Are you effectively backing up timelines to capture and incorporate patient feedback?

Although most sponsors are trying to incorporate patient input into trial design, industry standards do not currently exist. There are a myriad of ways to collect patient input and depending on the company, the therapeutic/patient population and the complexity of the protocol, there is no one-size fits all implementation model. What is being done? Where are sponsors having success? What is not working — and would it have worked under different circumstances?

CBI’s Patient-Centric Trial Design conference offers a unique opportunity to benchmark with industry leaders and to walk away with trial design strategies and techniques that will have a direct (positive) impact on drug development, all while protecting the scientific integrity of the trial.

Hear the Patient Voice — What Works and Doesn’t Work in Study Design?

Jennifer Ahlstrom, Founder, CrowdCare Foundation, Myeloma Crowd and mPatient Myeloma Radio

Jeri Burtchell, Founder, PartnersInResearch.org

Sarah E. Kucharski, Rare Disease Patient; CEO, Chairman and Founder, FMD Chat; Coordinator of ePatient Programs, Stanford Medicine X

“Putting the patient in the center of any program is key and it is important to learn from each other or help each other figure out how to do this effectively.”

— Previous Attendee, Associate Director, Clinical Trial Management, Endo Pharmaceuticals

A Great Place to Meet Your Market!

Take advantage of the best opportunity to meet potential clients face-to-face. Build relationships while demonstrating thought leadership and sharing expertise.

For more information on how to position your company as a sponsor or exhibitor, contact Robert Boucini at 339-298-2150 or email robert.boucini@cbinet.com.
Design Exercise — Marrying the Science with Patient Needs

- Collaboratively pick apart the protocol and begin creating alternative scenarios for a new protocol
- Determine impact on trial scope, budget and timelines in balance to more favorable enrollment/adherence
- Discuss and agree on a final protocol

There will be a 30-minute networking and refreshment break at 10:00am

12:00 Networking Luncheon

KEYNOTE ADDRESS
Role of Patients in Various Points in the Drug Development Continuum

Patients are more educated about their disease than ever before and as a result are becoming advocates in their own care. The challenge for sponsors is to operate within the intersection of science and patient centricity — a balance that is needed to be successful. How do you keep drug development moving while adapting to the new role of the patient? Additionally, as sponsors, we must capture fit-for-purpose patient insights and understand how best to utilize them to make an impact on the trial within the scope of the intended protocol. Patient insights can come from a variety of sources including patient KOLs, trial alumni, social networks, patient organizations, etc. This keynote address offers insight into capturing these insights from various points along the drug development continuum.

Paulo Moreira, Vice President, Global Clinical Operations, External Innovation, EMD Serono

2:00 Implications of the eParticipant on Scientific Integrity of Clinical Trials

Patients around the world are using the internet and social media to interact with healthcare professionals. While this has become an important piece of the patient journey, there are risks from the trial standpoint regarding eligibility, blinding and safety.
How does research need to change based on the new and upcoming use of social media? What can sponsors do to design a safe place for patients to connect without hurting the science? This thought-provoking session seeks to address these questions.

Craig Lipset, Head, Clinical Innovation, Pfizer Inc

2:45 Networking and Refreshment Break

Back Up Trial Timelines to Incorporate Patient Input into Trial Design

3:15 Why and How to Engage Patients in the Clinical Trial Process

Patients are the most motivated group to find cures, particularly for terminal diseases. If their drive and insights are channeled into productive contributions, research could advance at a significantly faster pace. Studies have been performed to identify reasons patients do not participate in clinical trials in response to increasing enrollment challenges. What are ways to engage patients so they will participate? In this session, learn what multiple myeloma patient Jennifer Ahlstrom is doing to overcome these barriers from a patient’s perspective, including:

- Creating an online internet radio show interviewing top myeloma researchers
- Developing a site to give a collective voice to patients
- Involving patients in crowd funding for myeloma research

Jennifer Ahlstrom, Founder, CrowdCare Foundation, Myeloma Crowd and mPatient Myeloma Radio

4:00 Clinical Trials as Products — Gathering Patient Feedback to Create Actionable Trial Design and Execution Strategies

Most industries conduct advanced research to learn more about the end-user (i.e., patients) and how they view the product, but the same can’t be said about the majority of drug development where the end-users aren’t involved until the trial is underway. Should we be surprised when trials under enroll or retention rates are lower than expected? Regulatory compliance and scientific integrity present challenges unique to drug development. This session provides:

- Results from polling clinical operations executives on:
  - the extent to which they are engaging patients in drug development
  - the reasons for not soliciting patient feedback
- Deep dive on a methodology to harness feedback and utilize patient data to create tools to capture data and disseminate it back to study teams
- Insights and case studies on experience to date

Matt Scott, Head of Clinical Solutions, PatientsLikeMe

4:45 Creation of Patient-Reported Outcomes Tool for Rare Non-Hodgkin’s Lymphoma

- Benefits of shifting patient centric research from traditional site driven protocols to a virtual platform
- Using PatientsLikeMe’s Open Research Exchange (ORE) to develop and share new health measures to better reflect patient experiences

Mitchell Nagao, Senior Director, Medical Head ASPIRE, Actelion Pharmaceuticals

5:30 Close of Day One

DAY TWO
Wednesday, February 4, 2015

7:30 Continental Breakfast

8:00 Chairman’s Review of Day One
Bruno Gagnon, Vice President, Clinical Operations, BioMarin Pharmaceuticals

8:15 PATIENT SHARK TANK® — If You Design It, Will They Come?

How do we ensure that the patient voice is amplified in the design of clinical trials? Join us as ePatient judges rate trial design elements exclusively from the patient and caregiver perspective. As organizations pitch their trial design elements or innovation, patient panelists ask targeted questions based on their experiences to understand how the design elements uniquely address patient needs.

Facilitator: Sarah Krüg, CEO, CANCER101; Executive Director, Society for Participatory Medicine

9:45 Networking & Refreshment Break
10:15 **Patient Risk in Clinical Trials — Who Should Decide Acceptable Levels and Why?**

- Why and how do we encourage the general public to care about clinical research?
- What do patients, healthy, ill, or without any other treatment option, stand to gain from enrolling in clinical trials?
- How do we adequately inform patients about clinical trial risks with regard for individual health literacy levels?
- How should the industry and individuals who work within it, respond to calls for early access to medications?

_Sarah E. Kucharski, Rare Disease Patient; CEO, Chairman and Founder, FMD Chat; Coordinator of ePatient Programs, Stanford Medicine X_

11:00 **Key Considerations when Incorporating an Early Access Program (EAP) into Trial Design**

Is expanded access a patient right? Recent social media blitzes and “right to try” laws are creating that expectation. Is this expectation realistic? What are the barriers that keep companies from creating these programs? How and when should companies decide on their corporate policy? How and when should they communicate it? This session offers an opportunity to discuss answers to these pressing questions.

_Barbara Wuebbels, Vice President, Patient Advocacy, Audentes Therapeutics (invited)_

11:45 **INNOVATION ADDRESS**

_The Patient Experience Doesn’t End with the Last Visit_

This innovation address discusses the principles that are driving new patient engagement strategies currently in development, focused primarily on what can be done after research volunteers have completed their part in a clinical research program. Eli Lilly shares their vision, progress to date and future objectives.

_Joseph Kim, Senior Advisor, Clinical Development Innovation, Eli Lilly_

Mr. Kim serves as a Senior Advisor in Clinical Development Innovation at Eli Lilly, focusing on developing and implementing innovative patient engagement solutions. He has spent over 15 years in the Pharma industry utilizing a unique approach that integrates his experiences working for Sponsors such as Shire and Merck, CROs, and technology vendors. He has a robust combination of experience that includes early and late phase clinical research, and a well known history of innovation in the clinical research industry, recognized as one of “20 Innovators Changing the Face of the Clinical Trials Industry” by CenterWatch in 2013.

12:30 **Networking Luncheon**

1:45 **Don’t Forget about the Investigator Site — A Key to Patient-Centricity**

Patient-centricity involves more than listening to patients. The needs of a site also need to be considered when designing optimized trials — Less time on tedious or unnecessary tasks enhances patient care. This case study highlights how to:

- Improve communication between sponsors and sites through technology
- Consider design elements from a site execution perspective
- Utilize site advisory committees to weigh in on design elements
- Leverage patient insights to inform site enrollment strategies

_Kelly Mckee, Associate Director, Clinical Research, Global Trial Optimization, Merck & Co., Inc_

2:30 **Understanding the Patient Experience — Financial and Logistical Considerations for Trial Conduct**

Conducting a study for a specialized population presents unique challenges when it comes to both logistical and financial operations. Timing of the trial and follow-ups need to be considered as well as how and how much financial assistance is needed. This session discusses critical points to consider before starting a trial and offers insights into solutions to date:

- What considerations need to be made for patient’s socioeconomic status?
- What is sufficient financial assistance?
- When does a site provide 1099 to the study subject?
- What if the patient is a minor?
- What if the patient is not a legal resident?
- What are acceptable forms of payment?
  * cash, check, gift card, rechargeable debit card
- How do you ensure trial logistics are feasible?
  * time away from family
  * missed school
  * invasive tests/procedures

_Fabian Sandoval, M.D., CEO & Medical Director, Emerson Clinical Research Institute, LLC_

3:15 **Close of Conference**
Patient-Centric Trial Design and Execution
Utilize Fit-for-Purpose Patient Insights to Improve Protocol Design and Trial Outcomes

FEBRUARY 3-4, 2015 • SONESTA HOTEL • PHILADELPHIA, PA

VENUE:
Sonesta Hotel Philadelphia
1800 Market Street
Philadelphia, PA 19103
Phone Reservations: (800) 766-3782
Hotel Direct Line: (215) 561-7500

ACCOMMODATIONS:
To receive CBI’s special discounted hotel rate online or by phone, please go to:
• Online: www.cbinet.com/patientcentric
• Phone reservations: (800) 766-3782 and mention CBI’s Patient Centric Trial.

Book Now! The Sonesta Hotel Philadelphia is accepting reservations on a space and rate availability basis. Rooms are limited, so please book early. All travel arrangements subject to availability.

Satisfaction Guaranteed:
CBI stands behind the quality of its conferences. If you are not satisfied with the quality of the conference, a credit will be awarded towards a comparable CBI conference of your choice. Please contact 800-817-8601 for further information. Advanced preparation for CBI conferences is not required.

Substitution and Cancellation:
Your registration may be transferred to a member of your organization up to 24 hours in advance of the conference. Cancellations received in writing on or before 14 days prior to the start date of the event will be refunded, less a $399 administrative charge. No refunds will be made after this date; however, the registration fee less the $399 administrative charge can be credited to another CBI conference if you register within 30 days from the date of this conference to an alternative CBI conference scheduled within the next six months. In case of conference cancellation, CBI’s liability is limited to refund of the conference registration fee only. CBI reserves the right to alter this program without prior notice. Please Note: Speakers and agenda are subject to change. In the event of a speaker cancellation, every effort to find a suitable replacement will be made without notice. The opinions of the conference faculty do not necessarily reflect those of the companies they represent or CBI.